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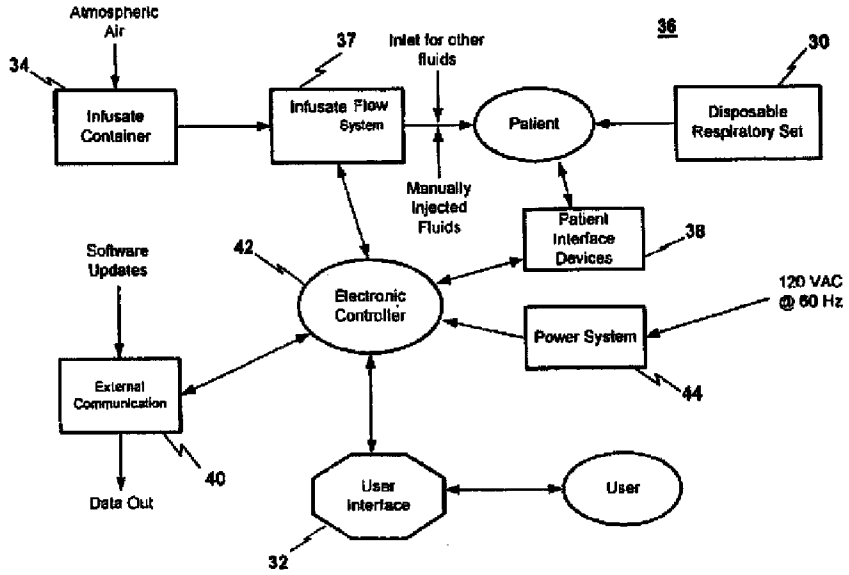
(54) Title: APPARATUSES AND METHODS FOR PROVIDING IV INFUSION ADMINISTRATION



(57) Abstract: An infusate cassette is described for use with an IV infusion system which controls the process of administering a drug to a patient. The cassette and other aspects of the infusion system may include disposable components, external redundant volume tracking, air removal and automated purge and prime capabilities, component removal lockout mechanisms, and/or redundant automated anti-free flow devices. An IV manifold comprising an imbedded high cracking pressure anti-free flow valve is also described for use with the infusion system. The cassette, IV manifold, and other aspects of the infusion system may be provides with quality assurance mechanisms for use with integrated IV infusion.

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APPARATUSES AND METHODS FOR PROVIDING IV INFUSION ADMINISTRATION

This application claims priority under 35 U.S.C. §119(e) to U.S. Patent Application Serial Number 60/308,592 filed July 31, 2001 and to U.S. Patent Application Serial Number 60/378,046 filed May 16, 2002, both of which are incorporated herein in their entirety.

FIELD OF THE INVENTION

The invention of this application relates generally to IV infusion of drugs to patients, and more particularly to aspects of an IV infusion system comprising an infusate cassette, an infusate container, and various quality assurance means.

BACKGROUND OF THE INVENTION

Mechanically controlled infusion of a liquid drug from a reservoir directly to a patient is a useful process of administering a drug. An electro-mechanically controlled infusion process often provides a much steadier and more accurate administration of a drug or infusate than is possible from a human giving injections. By maintaining precise control of the flow rate of drug, an electro-mechanically controlled infusion device may ensure that the concentration of the drug in a patient's circulatory system remains steadily within the drug's therapeutic range.

Certain known medical devices for controlling the infusion of a liquid directly to a patient utilize pumping mechanisms to deliver liquid drugs from a reservoir such as a syringe, a collapsible bag, or a drug container to a patient supply tube. One example of such a device, shown in U.S. Pat. No. 6,186,977, includes a liquid drug supply in a collapsible bag and an infusion pump, which draws the drug directly from the supply and moves it along a flow passage to a patient supply tube.

Certain of these medical devices further utilize drug pump cassettes, which provide a rigid housing and pressure plate that interact with the pumping mechanisms of the devices. These cassettes serve as intermediary devices between drug containers and patient supply lines. A typical cassette includes a passage, which is acted upon by the pumping mechanism of an infusion device to move the drug along to the supply line.

One example of a cassette for use with a drug pumping system, shown in U.S. Pat. No. 6,165,154, has a fluid passage and a collapsible pressure conduction

chamber for generating a pressure gradient to move drug along the passage. Another example of a cassette, shown in U.S. Pat. No. 6,202,708, provides a large chamber for mixing a powdered drug with a liquid solvent. This cassette also includes a pressure plate, which supports a fluid flow passage against which a peristaltic pump may act to move the liquid along to a patient delivery tube.

Certain liquid infusion devices which provide means for removing air that has entered their flow passages are also known. However, these devices often require an inefficient purging process which in turn requires human intervention and/or knowledge of the exact internal volume of all of the liquid passages in the system in order to flush air from the passages without losing excessive amounts of the drug.

There are also known drug infusion systems which are provided with computers or controllers that can track the volume of the liquid infusate remaining in a container by tracking internal encoder counts within the pumping mechanism. A problem with tracking volume based on internal effects, though, is that if there is an inconsistency with respect to a component within the infusion device, the calculated volume of drug infused may be incorrect and yet would nonetheless appear to be consistent with the operation of the device.

There are further drawbacks to the efficiency and safety of all of the aforementioned devices. One such drawback is that the known drug infusion devices may not allow for a cost effective means of disposing of those elements which come in direct contact with the drug. It may be beneficial from a quality control and patient safety standpoint to replace those parts of a liquid drug infusion device which directly contact the drug upon the completion of each infusion process. Disposal and replacement provide an efficient means of starting each infusion process with clean components that are free from residual infusate remaining from an earlier infusion or from vectors for cross-contamination from the previous patient. Some parts of the aforementioned devices, such as the drug pump cassettes, may be large and bulky and so might be expensive and clumsy to replace after single-patient use.

Another drawback of the above devices is that certain of their components, such as the drug containers, cannot be replaced during an infusion process, i.e., while the pumping mechanism is active, without introducing air into the system. Air may also be introduced into the systems if these components are accidentally removed from the device during an infusion process. Air bubbles that are entrained into the flow passages of a

direct-to-patient infusion system can be dangerous if introduced into the patient's circulatory system.

Deaths have resulted from erroneous delivery of potent pain killers such as morphine by infusion pumps. Thus, a means of controlling the infusion rate of a drug based on a measurement or inference of an effect of the delivered drug on the patient may be beneficial. Such a means of control may be especially desirable during outpatient, ambulatory, gastrointestinal, cardiac catheterization, imaging and other procedures at remote and/or minimally staffed or equipped locations such as, among others, office-based surgery, imaging, or dermatology suites and far-forward military medical outposts where anesthesia and analgesia are provided with the concomitant risk of loss of consciousness and apnea.

SUMMARY OF THE INVENTION

The present invention addresses the aforementioned drawbacks of existing drug infusion devices by providing an infusion system with an infusate pump cassette that may include disposable components, external redundant volume tracking, air removal and automated purge and prime capabilities, component lockout mechanisms, and/or redundant automated anti-free flow devices. The term "infusion system" as it is used herein may denote a stand-alone infusion pump that is not necessarily integrated with patient monitoring.

It is a further object of the present invention to provide a computer assisted IV infusion system with single-patient use disposable components to prevent potential cross-contamination and infusate carry-over from a previous infusion to a same or different patient. Components of this aspect of the invention that may be disposable may include, among other items, infusate containers, infusion tubing, pressure plates, infusion line connectors, cassettes, anti-reflux valves, high cracking pressure valves, IV manifolds and vascular access devices such as, among others, IV needles, cannulae and catheters.

The infusion system of the present invention may form part of a larger infusion system for computer assisted infusate administration that may include EKG pads or skin electrodes, and oxygen delivery, gas sampling and respiratory apparatuses, responsiveness query devices, and semi-automated modulation of infusion rate based on measured or inferred effects on the patient. The EKG pads or skin electrodes, oxygen delivery, gas sampling and respiratory apparatuses and responsiveness query devices may be disposable. The term "infusion system" as it is used herein may denote an infusion

pump integrated into a larger system that manages the administration of infusate based on data from patient monitoring devices.

The integrated computer assisted infusate administration system is applicable for use in, among others, sedation and analgesia and deep sedation procedures. An example of such a system could be the sedation and analgesia delivery system described in U.S. Patent Application Serial No. 09/324,759 filed June 3, 1999, the entirety of which is herein incorporated by reference. The sedation and analgesia system of Application No. 09/324,759 includes a patient health monitor device adapted so as to be coupled to a patient and generate a signal reflecting at least one physiological condition of the patient, a drug delivery controller supplying one or more drugs to the patient, a memory device storing a safety data set reflecting safe and undesirable parameters of at least one monitored patient physiological condition, and an electronic controller interconnected between the patient health monitor, the drug delivery controller, and the memory device storing the safety data set; wherein said electronic controller receives said signals and in response manages the application of the drugs in accord with the safety data set. The safety data set, as referred to by the electronic controller, may further include data regarding proper values for the identification and/or sources of drugs, supplies, components or attachments including the disposables listed above. Such identification may also be made by reading data from quality assurance modules accompanying the disposables.

It is a further object of the present invention that some of the disposable components are integrated into a single-use cassette for the transmission of infusate from containers to the patient. The cassette may be affixed to the infusion system with a single-motion snap-on action. The cassette is of a form so that its components align in the correct orientation with the permanent components of the system upon the single-motion snap on action. For example, a portion of the delivery conduit is positioned at the active portion of a pumping mechanism on the infusion system when the cassette is fitted into place.

The present invention allows for the infusate container to be removed and replaced during a given procedure without requiring the user to purge the infusion line of air. An infusate container lockout mechanism is provided to prevent removal of the container while the pump is running. To prevent free flow, various redundant infusion line lockouts automatically close off the infusate flow lumen when the cassette is not inserted into the infusion system. The lockouts are provided to guard against the

pumping mechanism transporting air to the patient and against the free uncontrolled flow of infusate by gravity feed to the patient. To prevent air from reaching the patient if the lockout mechanisms fail, an air in line (AIL) detector may be used as a back-up safety device.

The infusion system provides an efficient means of controlling the flow of infusate from an infusate container such as, among others, a vial, syringe or collapsible bag to a manifold connector where the infusate may be combined with an IV solution and/or other fluids before administration to the patient. Computer control allows accurate flow rates and precise control of those flow rates for infusion and purging procedures as well as automated purging without the need for the user to intervene or remember to purge the line. Flow rate accuracy, combined with knowledge of the internal volume in the IV infusion set (acquired, for example, via a quality assurance module associated with the set), ensures the conservation of expensive infusate such as propofol, which may be wasted during manual control of the same procedures.

The present invention further provides a cassette with a sheathed infusate container spike made of injection molded plastic with an automated free flow prevention feature. The spike remains sheathed if the cassette is not fully engaged with a mating surface of devices such as, for example, a pumping unit or a sedation and analgesia delivery system. In general, the infusate container will be upside down but the invention also contemplates the possibility of having the infusate container upright. The cassette of the present invention may include molded snap retainers or clips integral to the cassette in lieu of metal clips to hold peristaltic tubing in place, thus reducing parts count. A stopcock and/or IV manifold at the IV cannula or patient end, if present, may be made of, or shrouded in, soft materials so that the risk of a pressure-induced injury is reduced.

The automated sheathing of the spike when an infusate container is not mounted to the cassette minimizes the risk of accidental sharps injury. The design provides tamper-resistant inaccessibility to the spike when the spike is not inserted in an infusate container, to further minimize risk of accidental sharps injury. When the infusate container entry mechanism and/or the cassette are made of plastic, the design of those elements may be compatible with constraints imposed by injection molded tool design.

Upon removal of an infusate container from the cassette, a spike sheath re-deploys to sheath the spike. The movement of the spike sheath may be used to actuate a lever arm that rotates a stopcock such that an infusate lumen in a spike assembly is closed and infusate flow is prevented. Thus, after an infusate infusion, uncontrolled free flow of

residual infusate left in the peristaltic and intravenous tubing to a patient still connected to the cassette is prevented, e.g., when the cassette is removed.

A breakable fin on the cassette may be used as an indicia of the use status of the cassette. An air filter housing may be incorporated into a spike assembly to reduce parts count. A holder for the air filter media may also be incorporated in the spike assembly to further reduce parts count and manufacturing cost.

The cassette may be indexed to its mating surface by designing the cassette such that it can only mount onto its mating surface on the housing of an infusion system in a predetermined or singular orientation.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a perspective view of one embodiment of an infusion system for computer assisted infusate administration according to the present invention.

FIG. 2 is a schematic showing data flow according to one embodiment of the present invention.

FIG. 3 shows a top cross-sectional view of one embodiment of the cassette fitted with an infusion system according to the present invention.

FIG. 4 shows a front cross-sectional view of an alternative embodiment of a cassette extension with an infusate container in place thereon according to the present invention.

FIG. 5 shows a perspective view of one embodiment of a redundant volume tracking system according to the present invention.

FIG. 6a shows a perspective view of one embodiment of a cassette according to the present invention.

FIG. 6b shows a perspective view of one embodiment of a cassette with infusate delivery conduit according to the present invention.

FIG. 7 is a block diagram of mechanisms for redundant volume tracking according to the present invention.

FIG. 8 is a block diagram of mechanisms for the automatic shut off of the pumping mechanism according to the present invention.

FIG. 9 is a block diagram of certain parameters used with the quality assurance modules according to the present invention.

FIG. 10 shows one embodiment of the anti-reflux valve and IV manifold connector according to the present invention.

FIG. 11 is a block diagram of one embodiment of the liquid and air flow path between various components according to the present invention.

FIG. 12 shows a front cross-sectional view of one embodiment of a cassette extension with an infusate container suspended therefrom according to the present invention.

FIG. 13 depicts a perspective view of one embodiment of a cassette with integral spike sheathing and anti-free flow features according to the present invention.

FIGS. 14a and **14b** show different perspective views of a spike assembly with an integrated stopcock lever arm that interacts with a cassette according to the present invention.

FIG. 15 shows a cut-out view of one embodiment of a spike assembly attached to a cassette with a spike sheath omitted according to the present invention.

FIG. 16 shows a perspective bottom view of one embodiment of a spike sheath according to the present invention.

FIGS. 17a and **17b** represent perspective cut-out views of one embodiment of an anti-free flow device on a spike assembly interacting with protuberances on a spike sheath, in sheathed and exposed positions respectively according to the present invention.

FIG. 18 shows a perspective view of a cassette and a mating surface when the two are not yet touching according to one embodiment of the present invention.

FIG. 19 shows a perspective view of interaction between a cassette and a mating surface when the two are partially engaged according to one embodiment of the present invention.

FIG. 20 shows a perspective view of interaction between a cassette and a mating surface when the two are engaged and mated according to one embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The embodiments described below are not intended to limit the invention to the precise forms disclosed. The embodiments are chosen and described in order to explain the principles of the invention and its applications and uses, and thereby enable others skilled in the art to make and use the invention.

FIG. 1 shows an external view of an infusion system for computer assisted infusate administration **36** of the present invention. The system includes housing **26** for

user interface **32** and pumping mechanism **56** (shown in **FIG. 3**), as well as ports for the attachment or insertion of, infusate container **34**, detachable cassette **10** for receiving infusate container **34** and patient interface devices such as oronasal device **31** which may, for example, provide oxygen and/or capnometry or other respiratory monitoring. Infusate flows from the cassette **10** to a patient via intravenous infusion line or delivery conduit **27**. Intravenous fluids, or other fluids, if used, flow to the patient via separate infusion line **80**. Lines **80** and **27** merge at connector or IV manifold **72**. Fluid flows from connector **72** to the patient via a vascular access device such as, among others, an IV needle, cannula or catheter **84** that is inserted in a vein of the patient. Delivery conduit **27** may be removably or permanently attached to cassette **10** and/or connector **72**.

User interface **32** is connected to a microprocessor-based electronic controller or computer **42** (shown in **FIG. 2**) located within housing **26**. The electronic controller **42** may be comprised of available programmable-type microprocessors and other chips, memory devices, and logic devices on various boards. Various user interface devices include display device **33** which may be integrated into housing **26** of infusion system **36** which displays patient and system parameters and operation status of the infusion system **36**, a printer (not shown) which prints, for example, a hard copy of patient parameters indicating the patient's physiological condition and the status of the infusion system **36** and infusate flow with time stamps, and an optional remote control device (not shown) which permits a clinician to interact with the infusion system **36** from a distance. User interface **32** may include hard and soft buttons that allow the user to override an automated infusion process and manually control or interrupt the infusion as well as purge the infusion set of air or prior infusate.

FIG. 1 also shows respiratory set **30** which may be attached to infusion system **36** and which, along with oronasal device **31**, may be disposable. Preferably, the respiratory set is a single-patient or single-use disposable element that is removably attachable to the infusion system **36**. The infusion system **36** includes a connector port **39** within its housing **26** in which the respiratory set may be attached so that it is operably coupled with the electronic controller **42**.

FIG. 2 is a schematic with data flow showing the infusion management steps performed by electronic controller **42** in an embodiment of the present invention. A user interacts with user interface **32** that is in communication with electronic controller **42** whereby the user may input certain commands or program process sequences that are then stored in memory by the electronic controller **42**. The electronic controller **42** is in

communication with infusion system **36** which controls flow from infusate container **34**. Infusate flow system **37** may comprise pumping mechanism **56** (shown in **FIG. 3**), cassette **10** and delivery conduit **27**, and is capable of functioning as an autonomous infusion system or can be integrated into a larger system. The electronic controller **42** monitors and regulates the infusion rate based on input from the user, from control software that may incorporate drug state models, and/or from data collected from patient interface devices **38**. The various patient interface devices **38** can include one or more patient health monitors (not shown) that monitor a patient's physiological condition, such as a pulse oximeter, capnometer, blood pressure monitors, EEG, EKG, responsiveness monitor, airway pressure monitors, among others.

FIG. 2 also shows respiratory set **30** (which may be disposable and include oronasal device **31**) which is connected to a patient; a power system **44** which provides power to electronic controller **42**; and external communication device **40** which may be a printer and in communication with electronic controller **42** and which accept software updates and output data.

FIG. 3 shows a cassette **10** for the transfer of infusate from infusate container **34** (which may be sealed) to a patient. The cassette **10** provides a mechanical platform for anchoring infusate container **34** to the housing **26** and assures that the infusate container **34** remains at a fixed head height with respect to pumping mechanism **56**. The cassette **10** also assures that delivery conduit **27** is positioned and oriented properly with respect to pumping mechanism **56**. The cassette includes an extension **11** for receiving the infusate container **34** and maintaining the container's position during the infusion process.

In a particular embodiment of the invention, the cassette **10** receives a single infusate container **34** for each infusion process. At the conclusion of the infusion process or upon the near-depletion of the container **34**, the container **34** is removed and the cassette **10** may receive a new infusate container **34** for an extension of a prior infusion process. The delivery conduit **27** may be purged of any air and/or infusate from the prior infusion process. In an alternative embodiment, the cassette **10** may receive more than one infusate container **34** at a time. The cassette **10** may have multiple flow lumens (e.g., such as those shown in **FIG. 4** at **54**) to channel the infusate flow from each of the separate infusate containers into a single infusion system within the cassette **10** or infusion system **36**. A mechanism may be provided to restrict the infusate flow created by the pumping mechanism **56** so that infusate flows from one infusate container **34** at a

time for a sequential sequence or from more than one infusate container **34** at a time according to pre-determined proportions. Pumping infusate from multiple containers simultaneously allows an extended infusion run without halting for a purge sequence. Pumping infusate from multiple containers in concert allows separate and segregated sources of infusate to be used concurrently for a single infusion run. In a further alternative embodiment, multiple containers of the same infusate are provided with a single cassette **10** such that one container can be removed while infusate is flowing from another. Such an embodiment allows for an extended infusion process without halting for a purge sequence.

Still referring to **FIG. 3**, the extension **11** may include an attached infusate flow activation device **12** (which as further described below may be a spike or other sharp having internal lumens) for initiating the transfer of the infusate from the infusate container **34** to delivery conduit **27**. At the start of the infusion process, the infusate container **34** is placed onto the activation device **12**.

FIG. 3 also shows an opening **16** in the cassette where infusate flow lumen **54** (as shown in **FIG. 4**) within the extension **11** terminates. One end of pressure plate **20** is located near opening **16**. The pressure plate is rigid enough to provide a platform against which pump fingers **58** may operate. A rigid pressure plate also allows cassette **10** to be easily fitted onto its mating surface on housing **26** with a one-step snap on motion. In one embodiment of the present invention, the pressure plate **20** has a concave curve that bowls away from the opening in order to accept the curved face of pumping mechanism **56**. Alternatively, a flat pressure plate **20** and a flat face of a pumping mechanism **56** as well as other pressure plate profiles may also be used with the present invention.

FIG. 3 further shows an infusate delivery conduit **27** that is provided with the cassette **10** at opening **16**. Delivery conduit **27** is inserted over the male port in opening **16** to create an air-tight connection with the flow channel created by infusate flow lumen **54** (shown in **FIG. 4**). Delivery conduit **27** is positioned along the pressure plate **20** such that pumping mechanism **56** may act on it to move the infusate through the conduit, away from the infusate container **34**, and to the patient. The delivery conduit, which may be tubing, may be fixed in position along the pressure plate **20**. A structure to hold the delivery conduit **27** abutted against the pressure plate **20** should not interfere with the action of peristaltic pump fingers **58**. Several embodiments of such structure are contemplated for affixing the delivery conduit **27** to the pressure plate **20**. For example,

the conduit **27** may be ultrasonically welded or glued to the pressure plate **20** or it may be fitted within foam strip guides **60**, which are themselves fixed to the pressure plate **20**. The foam strip guides **60** by virtue of being compressible and collapsible do not interfere with the accuracy of the pumping mechanism **56** or the operation of pump fingers **58**. Alternatively, pieces of plastic tubing similar to delivery conduit **27** could be placed on pressure plate **20** above and below delivery conduit **27** such that they hold delivery conduit **27** securely against pressure plate **20** and collapse when squeezed by pump fingers **58**. At least a portion of delivery conduit **27** may be transparent so that the user can observe the infusate flow through the conduit and visually check for, among other things, entrained air or particulates in, or denaturation, separation or emulsification of, the infusate.

The pumping mechanism **56** may be a peristaltic pump with at least three movable fingers **58** which act upon delivery conduit **27** and against pressure plate **20** so as to create a pressure gradient within the delivery conduit. The pressure gradient causes the infusate to flow from the infusate container **34** into the bore **14b** (shown in **FIG. 4**) within the spike, then into the infusate flow lumen **54** (shown in **FIG. 4**) within the cassette extension **11**, then into the delivery conduit **27**, and then through manifold connector **72** (shown in **FIG. 1** and **FIG. 10**) and into vascular access device **84** inserted in a vein of the patient. Because the pump fingers **58** are external to the delivery conduit **27** and the entire infusion system tubing, the pumping mechanism **56** may be able to operate even if air is in the active pumping section of the delivery conduit **27**. The pumping mechanism **56** may be controlled manually or by the electronic controller **42** (shown in **FIG. 2**) of an infusion system **36** and may be set at a given flow rate or at a specified gradient, rate of change over time or time profile of infusate flow rates.

FIG. 3 also shows spring-loaded clamp or pinch valve **82** which acts as a free flow prevention device to halt the unchecked or free flow of infusate to the patient by gravity when the cassette **10** removed from contact with the pumping mechanism **56**. Clamp **82** pinches a portion of conduit **27** closed when it is not being kept open, e.g. by contact with housing **26**, pumping mechanism **56** or infusion system **36**.

As shown in **FIG. 3**, the cassette **10** may also include one or more extensions such as snap locks **22** and **23** which provide mechanical attachment to housing **26** such that the cassette **10** may be fixed in place relative to its mating surface and pumping mechanism **56**. In a particular embodiment, these extensions fit into slots **22a** and **23a** on the mating surface of housing **26** allowing for a snap-on single motion

attachment of the cassette **10**. The cassette **10** may also include finger grips **24** for gripping cassette **10** and guiding it into its designated place within the housing **26**. When finger grips **24** are squeezed together, snap locks **22** and **23** are spread apart allowing the cassette to be placed into slots **22a** and **23a**.

FIG. 4 shows a particular embodiment of infusate flow activation device **12** in which it is an upright spike for piercing a resealable stopper **13** of an inverted infusate container **34**. The spike **12** includes bore **14b** which creates an air-tight opening in the container **34** out of which the infusate may flow. Extension **11** of cassette **10** contains infusate flow lumen **54** provided between bore **14b** and infusate flow opening **16** in the cassette **10**. One end of delivery conduit **27** may connect to opening **16** while the other end may be attached to connector **72** (shown in **FIG. 1** and **FIG. 10**). Extension **11** may also contain an air flow lumen **50** between another bore **14a** in spike **12** and an opening to atmosphere through inlet **18**.

Infusate container **34** is generally inert to the infusate and impermeable to atmospheric contaminants. The container **34** is capable of protecting the infusate from outside contamination prior to and during the infusion process. Preferably, infusate container **34** is a rigid vial of invariable volume, though a flexible container such as a collapsible IV bag is also contemplated for use with the present invention. The infusate container **34** may have at least one transparent portion to allow visual assessment of the infusate's condition and volume. The infusate container **34** may also include a built-in gripping device such as a molded tab (not shown) by which a user can hold and transport the container without contaminating its surface. Preferably, self-sealing stoppers **13** are used with infusate containers that are to be removed from the cassette after use. Self-sealing stoppers provide air-tight piercing, prevent infusate spillage, and help to prevent the infusate from being compromised due to evaporation or contamination.

Still referring to **FIG. 4**, extension **11** may include a one-way or pressure relief valve **46** through which atmospheric air is introduced into infusate container **34** in order to prevent excessive vacuum (that might interfere with infusion) from developing above the infusate's meniscus as the infusate flows out of the container. Air flow lumen **50** is provided between one-way valve **46** and bore **14a** in spike **12**. Because in the embodiment depicted in **FIG. 4** infusate can flow by gravity along air flow lumen **50** to the atmosphere, certain embodiments are contemplated to prevent infusate from leaking out of the air flow lumen **50** while still allowing air to bleed inside the infusate container **34** to prevent formation of an excessive vacuum. In one of these embodiments, the

mechanism to prevent infusate spillage from bore **14a** is a one way valve **46**. One-way valve **46** only allows atmospheric air into air flow lumen **50** and does not allow any infusate which has leaked through bore **14a** to escape the cassette **10**.

In a further infusate leakage prevention embodiment, a hydrophobic filter **47** is provided with air flow lumen **50** in the extension **11**. The hydrophobic filter **47** prevents any infusate which has leaked into air flow lumen **50** of the spike **12** from flowing out of air inlet **18** of the cassette **10**.

In a further infusate leakage prevention embodiment, bore **14b** is a wide bore and bore **14a** is a narrow bore. Narrow bore **14a** is in communication with air flow lumen **50** in the extension **11** while wide bore **14b** is in communication with infusate flow lumen **54** of the extension **11**. The difference in capillary action caused by the different bore sizes causes the liquid infusate in the infusate container **34** to tend to flow through wide bore **14b** and into infusate lumen **54** only. Capillary action hinders the flow of infusate into the narrower air flow lumen. In an additional infusate leakage prevention embodiment, air flow lumen **50** contains a half-moon-shaped well **52** so as to restrict the flow of any infusate that does leak into air flow lumen **50** from making it to air inlet **18**.

An air filter **48** may be provided with air inlet **18** to prevent particulates in atmospheric air from entering air flow lumen **50** inside the extension **11** and inside infusate container **34**. Air filter **48** may be capable of screening out microbial matter including bacterial and viral particles.

In an alternative embodiment of the present invention, the infusate container **34** may include a pre-attached spike **12** and the container-spike set may be inserted as a unit onto the extension **11**. In a further alternative embodiment, the cassette **10** with extension **11** may include a pre-positioned infusate container **34** with an intact, i.e., not punctured, seal **13** which may be spiked (e.g., manually) immediately prior to activation of the infusion system. With such embodiments, the entire cassette-infusate container assembly may be fixed to the infusion system as a single unit, activated, and used and then may be subsequently removed from the housing **26** (shown in **FIGs. 1** and **5**) and disposed of as a single unit.

FIG. 5 shows an array **70** of photo-emitter cells and photo-detector cells, which may be an element used in an alternative redundant volume tracking method according to the present invention. Such an array may be provided with the cassette **10** or as part of housing **26**. Each photo-emitter cell emits light directed at the infusate container **34**. The difference in reflection of the emitted light depending on whether it

impinges on air or infusate, especially milky infusates like propofol, is used to track the meniscus. Emitted light which reflects back from the liquid inside of the container is detected by a photo-detector cell. The detector cells are capable of receiving reflected light from the infusate and are arranged in a pattern, such as a column, whereby if a particular detector cell receives a certain amount of reflected light, then it is below the meniscus of the infusate and whereby if the particular detector cell receives a different amount of reflected light, then it is above the meniscus of the infusate. The photo-detector cells can measure reflected light when they are on the same side of the infusate container **34** as the emitters or transmitted light when the detectors are on the opposite side of the emitters. Each cell of the array is in communication with an electronic controller **42** (shown in **FIG. 2**) and the controller **42** determines where the meniscus is within the infusate container **34** by identifying the region where there is a sharp transition in reflected or transmitted light. Meniscus tracking allows independent calculation of how much infusate remains in the infusate container **34** based on the initial volume of the infusate in the container **34**. The initial volume of the infusate in the container **34** may be encoded as a volume value and/or a particular meniscus level corresponding to a full container and/or a container characteristic such as cross-sectional area for a given container size on a quality assurance module ("QAM") **35** located on the given container **34**. QAM **35** is described in more detail below with regard to **FIG. 9**. A mechanism is provided to read the information on the QAM **35** and transmit among others data related to the initial volume to the electronic controller **42**. The photo emitter/detector pairs of array **70** may be staggered in two or more separate arrays to provide more spatial resolution.

FIG. 5 also shows an alternative embodiment of a free flow prevention device that may be provided with the present invention. Snap lock **23** of cassette **10** contains a slit **19** through which delivery conduit **27** may be placed. Cut-outs **21** are provided at each side of the slit **19** to allow the slit **19** to be forced wide apart such that when the cassette **10** is placed into proper position on to housing **26** a spreader piece **92** located on housing **26** spreads the fingers of snap lock **23** allowing the unrestricted flow of infusate through delivery conduit **27**.

Still referring to **FIG. 5**, housing **26** may include mechanical receptacle **66** for receiving and supporting the infusate container **34** as the infusate is drawn out of the container **34**. The receptacle **66** may be a particular size capable of receiving a

particularly sized infusate container **34** or it may be structured so as to receive containers of variable sizes.

FIG. 5 also shows an embodiment of an infusate container removal lockout mechanism **68** that may be provided with the housing **26** to prevent the removal of container **34** while the pumping mechanism **56** (shown in **FIG. 3**) is running. When in a locked position, mechanism **68** slides out of housing **26** and mechanically prevents removal of the infusate container **34** from the cassette **10**. Mechanism **68** may be in communication with the infusion system electronic controller **42**, which will only signal the pumping mechanism **56** that it may run when the lockout mechanism **68** is in a locked position. When mechanism **68** is in an unlocked position and retracted, the infusate container **34** may be physically removed from the cassette **10** and the electronic controller **42** will signal the pumping mechanism **56** to halt the infusate flow. Once a new infusate container **34** is inserted on the cassette **10** and the lockout mechanism **68** is returned to a locked position, the electronic controller **42** will again signal the pumping mechanism **56** that it may run. If the electrical power system **44** (shown in **FIG. 2**) or software to controller **42** fails, mechanism **68** can be manually pushed back into housing **26** to allow removal of container **34**. This feature of the present invention may remove the need for a purging sequence each time an infusate container **34** is removed and replaced by another container containing an infusate with the same identity and concentration as the infusate of the prior container.

In certain embodiments, the infusate container lockout mechanism **68** may be implemented by software running on controller **42**. A request for removal of the infusate container **34** is received by the software. The software checks whether infusion is ongoing and may decide based on the context and prevailing conditions whether to stop infusion to allow infusate container removal or allow infusion to continue and prevent infusate container removal, and depending on the decision may send an appropriate command to an actuator that can prevent infusate container removal to either allow or prevent manual removal of the infusate container **34**.

FIG. 6a shows a further perspective of cassette **10** where the cassette is not attached to housing **26**. Each of finger grips **24**, pressure plate **20**, opening **16**, spike **12** having bore **14**, air inlet **18**, snap locks **22** and **23**, slit **19**, and cut-outs **21** (all described in detail above) are shown.

FIG. 6b shows an alternative embodiment of cassette **10** in which spike **12** is attached to delivery conduit **27** and can be removed from cassette **10** so that the cassette

itself might be reusable with a new spike assembly **98**. Spike assembly **98** fits into conduit **27**, which fits into slot **96** of the cassette **10**. When the cassette **10** is placed against housing **26** (not shown), the housing **26** helps to keep spike set **98** securely held within slot **96**.

FIG. 7 illustrates various mechanisms for tracking the volume of infusate pumped out of the infusate container **34** during the infusion process. Methods for volume tracking provide redundancy to the volume calculated by the infusion system electronic controller **42** from the cycles of the pumping mechanism and the duration of the infusion so that the accuracy of the pumping mechanism's **56** flow rate may be verified and compensated for. This redundancy helps ensures a dependable and accurate flow rate of infusate into the patient.

One such mechanism for redundant volume tracking utilizes scales **86** which measure the weight of the infusate container **34** as it is in contact with the infusate flow activation device **12**. The scales **86** may be provided with the cassette **10** or as part of the infusion system **36**. The scales **86** are in communication with the electronic controller **42** which receives either continuous or periodic data on the weight of the infusate container **34** and its remaining contents. As infusate flows out of the container **34**, the weight decreases and the electronic controller **42** calculates the corresponding decrease in infusate volume from a preprogrammed set of infusate density data. By monitoring the change in volume over a given amount of time, the average flow rate over that given amount of time may also be calculated.

Another volume tracking mechanism is the photo emitter/detector array **70** for meniscus tracking described above with reference to **FIG. 5**.

Further volume tracking may be provided by tracking internal encoder counts **94** and **96** of the pumping mechanism **56**. Because most pumps use a motor to drive the pumping mechanism, there is typically a set volume of infusate delivered with each revolution or cycle of the pump's motor. If an encoder mechanism, such as a set of optical emitter/detector cells capable of detecting the passage of slots in the pump's cam, is provided with the pump, each revolution of the pump's motor can be detected. The electronic controller **42** can multiply the number of revolutions per minute of the pump's motor by the volume of infusate delivered per revolution to derive the infusion rate in volume per minute. The controller **42** can then integrate flow rate over time to calculate the total volume infused over time and derive average flow rate too.

FIG. 8 shows various optional methods for alerting the electronic controller 42 of reason to shut off the pumping mechanism 56. These methods help to prevent air from being pumped into a patient's blood circulation and help to prevent an incorrect (e.g., expired, previously used, or unrecognized) infusate or an incorrect dose from being administered to a patient.

In one of these methods, the user manually signals for a pump shut down if air is observed traveling towards the patient. The user interacts with a user interface 32 (shown in FIG. 1) which is in communication with the electronic controller 42. An air-in-line detector 90 may also be provided within the infusion system 36 to sense air bubbles within the infusate. The air-in-line detector 90 is in communication with the electronic controller 42. The electronic controller 42 may be programmed to send a signal to the pumping mechanism 56 to terminate the flow rate upon notice of a signal from the air-in-line detector 90. The conduit or PVC tubing 27 may then be purged of air.

In another of these methods, at least one occlusion detector 91 is provided with the cassette 10 or with the infusion system 36 to sense via associated pressure changes whether a kink or obstruction to flow is present in the delivery conduit 27. The occlusion detector 91 is in communication with the electronic controller 42 and sends a signal to the controller 42 when such an obstruction is detected. The controller 42 may be programmed to send a signal to the pumping mechanism 56 to terminate the flow rate upon notice of a signal from the occlusion detector 91.

In yet another of these methods, an air-entrainment lockout mechanism 93 is provided with the cassette 10 or with the infusion system 36. An air-entrainment lockout mechanism 93 is triggered by the removal of an infusate container 34 from the cassette 10 while the pumping mechanism 56 is running. Once triggered, the air-entrainment lockout mechanism 93 halts the flow of infusate within the cassette 10.

An example of an air-entrainment lockout mechanism 93 is a micro-switch located on or near the infusate flow activation device 12. When the infusate container 34 is removed from the activation device 12 it triggers the micro-switch to send a signal to the electronic controller 42. The micro-switch may be a spring-loaded button that is depressed as long as the infusate container 34 is on the activation device 12 and is released when the container 34 is removed, it may be a spring-loaded button positioned in such a location as to be depressed by the surface of the infusate container 34 as the container is removed, or it may be an electronic sensor such as an optical,

electromagnetic, inductive or capacitive sensor that registers when the infusate container **34** is removed.

An example of an infusate container removal lockout mechanism **68** and pump **56** management with respect to such a lockout mechanism is described above with respect to **FIG. 5.**

Still referring to **FIG. 8**, in a further particular embodiment, a cassette removal lockout mechanism **95** may be provided with the infusion system **36** to prevent the removal of the cassette **10** while the pumping mechanism **56** is running. When in a locked position, the mechanism **95** mechanically fastens the cassette **10** to housing **26**. The mechanism **95** may be in communication with the electronic controller **42**, which will only signal the pumping mechanism **56** that it may run when the lockout mechanism **95** is in a locked position. When in an unlocked position, the cassette **10** may be physically removed from the housing **26** and the electronic controller **42** will signal the pumping mechanism **56** to halt the infusate flow. Once a new cassette **10** is fitted within the housing **26** and the lockout mechanism **95** is returned to a locked position, the electronic controller **42** will again signal the pumping mechanism **56** that it may run. The mechanical cassette lockout mechanism **95** may be readily implemented by manually operated or motorized brackets, locks, twist locks, cams, levers, or any mechanical part that, when extended, physically prevents removal of the cassette. Sensors such as, among others, microswitches, proximity sensors, capacitive, magnetic, Hall effect, optical and inductive sensors may monitor the position of the manually operated or motorized cassette lockout mechanisms **95** and may communicate this data to controller **42**.

The cassette lockout functionality may also be implemented via software (which can be run on electronic controller **42**) whereby the software receives a request or indication of a request to allow removal of the cassette **10**, then checks the prevailing conditions (e.g., among others, whether infusate is being infused, whether an end of case has been signaled, whether the cassette **10** has been flagged as non-QAM compliant), and then allows the cassette **10** to be removed (manually or automatically) if it is safe to do so. In normal operation of the software implementation, the cassette **10** may only be removed via a request to the control software. In the case where the cassette **10** is manually removed, the software may control a motorized lockout mechanism **95** that can not be manually activated in normal operation. In an emergency, the user is allowed to override the software and remove the cassette **10** after at least one warning message that

the user has to acknowledge. Different ways to combine mechanical and software cassette lockout features into hybrid designs will be known to one skilled in the art.

In yet another of the optional methods for alerting the electronic controller **42** to shut off the pumping mechanism **56**, various QAMs **35** which can be attached to the cassettes **10** and containers **34** are contemplated which store information to be communicated to the electronic controller **42**. If a parameter recorded on a QAM **35** is out of a preprogrammed range stored in memory by the electronic controller **42**, then the controller **42** may send a signal to the pumping mechanism **56** to terminate or not initiate infusion.

FIG. 9 is a block diagram of certain parameters that the infusate container QAM **35** and cassette QAM **35** may store. Tags on the infusate container **34** or cassette **10** may store such parameters as the identity, concentration, initial volume or meniscus height of an infusate, characteristic dimensions or volumes of infusate containers, container identification, internal volume of the infusion set and cassette **10**, density of the infusate, serial number, batch number, expiration date, address such as a Universal Resource Locator (URL) and manufacturer identification in a barcode or RFID integrated circuit for example. Examples of such tags and QAMs and their uses with integrated infusion systems are described in U.S. Patent Application No. 10/151,255 filed May 21, 2002 and Application No. 60/324,043 filed September 24, 2001, each of which is incorporated herein by reference.

The electronic controller **42** receives the parameter data from the QAMs **35** and processes it to determine the initial conditions of the infusion setup. The controller **42** may use infusate identity data encoded on a QAM **35** to authenticate product source and quality and ensure that the particular infusate to be infused is the infusate intended for the current patient. When combined with a hospital information system that may store such data as, among others, the history and physical record and known allergies of a patient, the inadvertent administration of infusate contra-indicated for the patient may be flagged and averted.

The electronic controller **42** may also use the infusate identity information encoded on infusate container or cassette QAMs **35** to determine when cross-contamination may occur. The controller **42** may store in memory the identity and concentration of a prior infusate in use and the identity and concentration of a subsequent infusate to be used with the same cassette **10** and infusion system **36**. If the stored identity or concentration of the subsequent infusate is different from the prior infusate, the

electronic controller **42** may automatically initiate a purging sequence to clear any residual infusate from the prior infusion sequence from the system **36**.

In a particular embodiment, the electronic controller **42** uses data from the QAMs **35** to coordinate an automated purging or priming sequence. A QAM **35** on the cassette **10** may store the internal volume between the infusate container **34** and vascular access device such as, among others, the internal volume of the infusate flow lumens in the cassette **10**, delivery conduit **27** and IV manifold **72** (**FIG. 10**). The electronic controller **42** records these internal volumes or their sum from the QAMs **35** and signals the pumping mechanism **56** to cause a volume of infusate in excess of the sum of the internal volumes to flow through the infusion set to clear any air or prior infusate remaining in the lines. An automated purging sequence allows for the precise control of the volume of infusate pumped through the IV system during a purge sequence so that just enough volume of infusate is pumped to assure that the infusion set is free of air or prior infusate. Such a purging or priming sequence performed manually may result in a greater than necessary volume of infusate being pumped out of the infusion system resulting in wasted infusate and time. The automated aspect of the purging sequence automatically reminds a user to purge or prime an IV set preventing a hazard that may result from an error of omission; it also provides an "initiate and forget" benefit whereby a user can move on to other tasks while a purge is occurring, after initiating a purge sequence.

Preferably, the electronic controller **42** references a clock **90** (**FIG. 9**) to establish the start time and duration of each infusion run. The controller **42** may also use the clock **90** to determine when pre-programmed events such as pump flow rate or infusate container changes should occur. The controller **42** may also use the clock **90** and the infusion rate over a given time period to determine how much infusate is left in the container **34** so as to shut off the pump **56** when the volume of infusate remaining in the container **34** is low and alert the user.

FIG. 10 shows an anti-reflux valve **77** on connector **72** connecting delivery conduit **27** with tubing **80** from the IV solution, or other fluid, container **78** and vascular access device **84**. Anti-reflux valve **77** prevents the retrograde flow of infusate from tubing **27** into IV tubing **80**.

A check valve **76** that is part of connector **72** prevents back flow of fluid from tubing **80** up infusate line **27**. Check valve **76** can also operate as an automated free flow prevention device by deliberately increasing its cracking or opening pressure such

that it is higher than the highest hydrostatic pressure generated by a spiked and full infusate container **34** with conduit **27** fully extended to its highest possible elevation. The design thus requires pumping mechanism **56** to generate more pressure than the opening pressure of valve **76** for infusate to flow to the patient. If the pump mechanism **56** (shown in **FIG. 3**) is not in contact with conduit **27** and pressure plate **20**, when cassette **10** is removed from housing **26** or infusion system **36** for example, infusate flow will stop because the highest hydrostatic head that can be generated will be lower than the cracking pressure of valve **76**.

In an alternative embodiment, connector **72** may also include a stopcock or resealable injection port **74** capable of accepting a syringe tip or needle and allowing the direct injection of infusate or fluids therefrom. A vascular access device **84** may be inserted into the patient's vein. Preferably, the vascular access device is a single-patient or single-use disposable element that is removably attachable to the connector **72**.

FIG. 11 shows a block diagram of an embodiment of the present invention and depicts the infusate and atmospheric air flow pathways through the elements of **FIGs. 3** and **10** described above. Pinch valve **82** is open when the cassette **10** is snapped onto housing **26** or infusion system **36**. As soon as cassette **10** is snapped off, the spring in pinch valve **82** extends and closes off IV line **27**. The purpose of pinch valve **82** is to prevent free flow of infusate by gravity to the patient, when flow through conduit **27** is no longer being controlled by pumping mechanism **56** because conduit **27** is no longer in contact with it.

FIG. 12 shows an alternative embodiment in which infusate flow activation device **12** allows transfer of infusate from an upright infusate container. An elevator **94** is used to raise upright infusate container **34** into communication with the activation device **12**. Preferably in this embodiment, an inverted spike is used as the activation device **12**. If the infusate container **34** is placed upright as in **FIG. 12**, the possibility of the liquid contents flowing out by gravity via an air venting lumen is eliminated.

Particular alternative embodiments of the cassette **10**, an anti-free flow device, an air entrainment lockout mechanism, means of securing tubing to the cassette with a minimum of individual parts, quality assurance tags, as well as a means for sheathing the infusate flow activation device (or spike) **12** when it is not in use, and stopcocks made of, or shrouded in, soft materials will now be described.

FIG. 13 shows a perspective view of a particular embodiment of a cassette 150 according to the present invention having a pressure plate 152. Pressure plate 152 may include molded snap retainers 154 or other such means of holding delivery conduit 27 or peristaltic tubing (not shown for clarity) in place against the plate. A peristaltic pumping mechanism 56, such as that shown in FIG. 3, may be provided that contacts the tubing and abuts up against the pressure plate 152. Cassette body 156 may contain a cavity 176 (shown in detail in FIG. 15) that receives a slidably mounted spike sheath 158 that is shown in a deployed position over a spike in FIG. 13. Cassette body 156 is constructed so as to allow spike sheath 158 to slide down and expose a spike 163 (shown in detail below with reference to FIGs. 14a and 14b) if cassette 150 is fully engaged with mating surface 200 of the system 36 (as shown in FIG. 18) and is also constructed so as to not allow sheath 158 to slide down if cassette 150 is not fully engaged with surface 200. In particular embodiments of this invention, then, when a new or used cassette 150 is not mounted to mating surface 200, spike sheath 158 will always be deployed to sheath spike 163 and prevent accidental sharps injury. The cassette 150 may then be disposed in a contaminated wastebasket after use with minimized concern about a potential for accidental sharps injury by an exposed spike. A groove 192 may be included on both spike sheath 158 and cassette body 156 to provide clearance for peg 202 of surface 200 (shown in FIG. 18) that fits into groove 192. A breakable fin may be provided on cassette 150 to act as an indicia of use status of cassette 150. The cassette 150 may also be constructed with contoured ridges that provide a better grip for handling the cassette.

FIG. 14a is a perspective view of an embodiment of a spike assembly 160 which may be fitted to cassette 150 and to peristaltic tubing at connector 164. Spike assembly 160 includes spike 163 and may include any or all of air filter housing 162, tapered outlet connector 164 for connection to peristaltic tubing (or other infusion conduit) and lever arm 166 or other like means for actuating a stopcock 168 (FIG. 14b). Spike 163 may include lumens 14a (air venting lumen) and 14b (infusate flow lumen). Air flows via lumen 14a into an infusate container when placed over spike assembly 160 and spiked. This air flow may prevent vacuum buildup inside an infusate container when the container contents are emptied during infusion. Air filter housing 162 may house a filter element (not shown) that filters out airborne disease organisms from the ambient air that flows into the infusate container via lumen 14a. Air filter housing 162 may be designed so as to eliminate the use of an air filter media holder that is traditionally used to

contain the air filter media, further reducing parts count and cost of manufacture for the apparatus of the present invention. When lever arm **166** is in the up position as is shown in **FIGs. 14a and 14b,** stopcock **168** is rotated such that infusate lumen **14b** is closed. A closed infusate lumen **14b** prevents free flow of residual infusate left in peristaltic and intravenous set tubing and prevents potential entrainment of air emboli into the patient's bloodstream in situations where a used cassette **150** is removed from mating surface **200** while the intravenous set tubing is still connected to a patient.

FIG. 15 depicts a cut-out perspective view of cassette body **156** with spike sheath **158** removed. A cavity **176** in cassette body **156** is designed to accept spike sheath **158**. Spike assembly **160** is attached to a mounting flange **170** which is incorporated in or itself attached to cassette body **156**. Mounting flange **170** holds spike assembly **160** stationary relative to cassette body **156,** especially along a vertical axis such that an infusate container may be pushed onto spike assembly **160**. A movable member **172** forms part of the wall of cavity **176** and may be made movable by slits **178** cut below and above member **172**. Member **172** may have a groove **192** having end **174**. Peg **175** on movable member **172** engages with a notch **184 (FIG. 16)** or other surface of spike sheath **158**. Movable member **172,** when in a normal resting, or retracted, position, engages notch **184 (FIGs. 18** and **19)** in spike sheath **158** with peg **175** thereby preventing vertical movement of spike sheath **158**. When movable member **172** is in a deployed position, peg **175** no longer engages notch **184 (FIG. 20),** thereby allowing vertical displacement of spike sheath **158**. Movable member **172** is deployed when cassette **150** is substantially engaged with mating surface **200**. A peg **202** may be mounted on mating surface **200** in a position so as to deploy movable member **172** by pushing on end **174** of groove **192,** when cassette **150** is placed against mating surface **200**.

Still referring to **FIG. 15,** vertical displacement of spike sheath **158 (FIG. 13)** allows for each or both of the sheathing and unsheathing of spike **163** and the activation or deactivation of an anti-free flow device. For example, when sheath **158** is in an up position, spike **163** is sheathed by spike sheath **158** and a stopcock **168** is closed thereby preventing free flow of infusion liquid through spike assembly **160**. When sheath **158** is in a down position, spike **163** is unsheathed and stopcock **168** is open thereby allowing the flow of infusion liquid through the spike assembly **160**.

FIG. 16 shows a perspective view of spike sheath **158** which may include portion **190,** opening **188** to let spike **163** go through spike sheath **158** and protuberances **182** and **186** that engage with lever arm **166 (FIG. 14b)** to close and open stopcock **168**

respectively as spike sheath **158** travels up and down (**FIGs. 17a** and **17b**). At the top of portion **190**, a step **180** may be provided with a lip **191** which engages with an infusate container holder (not shown).

In a particular embodiment, the infusate container holder engages with step **180** and lip **191** of spike sheath **158** as cassette **150** is engaged to mating surface **200** (**FIGs. 18-20**). As movable member **172** (**FIG. 15**) is deployed to allow downwards travel of spike sheath **158**, the infusate container holder engages with spike sheath **158** to prevent unplanned downwards travel of the sheath. When the infusate container holder and spike sheath are interlocked, the spike sheath cannot travel down if the infusate container holder is not traveling down. Therefore, in such an embodiment, it is not possible to manually depress the spike sheath and expose the spike, when the cassette is fully engaged to its mating surface.

The infusate container holder is presented to the spike assembly **160** with an inverted infusate container to be spiked when the infusate container holder is moved down against the spike sheath **158**. If there is no infusate container in the infusate container holder, downwards travel of the infusate container holder may then expose the spike, posing a risk of a sharps injury. Particular embodiments of the invention check for the presence of an infusate container before allowing downwards travel of the infusate container holder. Checking for the presence of an infusate container may be implemented with sensors, including QAMs **35** (described above with reference to **FIG. 11**) and/or software or via mechanical means. The invention may also check if the infusate container is valid, e.g., of known origin and quality control and not past its expiration date.

Still referring to **FIG. 16**, when the infusate container holder is moved down, spike **163** is unsheathed through opening **188** and pierces the infusate container stopper thereby placing lumens **14a** and **14b** inside the inverted infusate container. The infusate container holder may engage the lip **191** and step **180** of spike sheath **158** such that when the infusate container holder is moved up to unspike an infusate container, the infusate container holder drags spike sheath **158** upwards and re-sheaths spike **163**. A cut-out **194** in spike sheath **158** may be included to provide clearance for mounting flange **170** (**FIG. 15**) when spike sheath **158** travels downwards. A groove **192** on portion **190** (**FIG. 16**) may be provided with groove **192** of movable member **172** so as to accept edge **204** of peg **202** that is provided with mating surface **200** (**FIG. 18**). Edges **189** on both sides of portion **190** (**FIG. 16**) prevent spike sheath **158** from rotating within cavity **176**

such that spike sheath **158** is only free to move in a vertical axis. Edges **189** also act as guides for vertical travel of spike sheath **158**.

FIG. 17a shows how spike sheath **158** deploys upwards to sheath spike **163** while protuberance **182** engages with lever arm **166** to close stopcock **168** thus preventing flow in infusate lumen **14b** of spike **163**. **FIG. 17b** shows how spike sheath **158** retracts downwards to expose spike **163** while protuberance **186** engages with lever arm **166** to open stopcock **168** thus allowing flow in infusate lumen **14b** of spike **163**.

FIG. 18 shows part of cassette body **156** oriented for engagement with mating surface **200** but not yet contacting the surface. Peg **202** includes edge **204** that slides along groove **192** (**FIG. 16**) on cassette body **156** and on portion **190** (**FIG. 16**) of spike sheath **158**. Peg **202** may also include a protuberance **206** that abuts against end **174** (**FIG. 15**) to deploy movable member **172** when cassette **150** is fully engaged with mating surface **200**. Protuberance **206** travels along groove **192**. A cutout behind protuberance **206** on peg **202** may be included to allow spike sheath **158** to travel downwards without catching on peg **202**.

FIG. 19 shows part of cassette body **156** partially engaged with mating surface **200**. Edge **204** of protuberance **206** (**FIG. 18**) of peg **202** is shown engaged in groove **192** on portion **190** (**FIG. 16**). Spike sheath **158** is still prevented by movable member **172** (**FIG. 15**) from moving downwards and exposing spike **163**. The infusate container holder (not shown) is engaging step **180** and lip **191** of the spike sheath (**FIG. 16**).

FIG. 20 shows cassette body **156** substantially engaged with mating surface **200** so as to deploy movable member **172** (**FIG. 15**). Protuberance **206** of peg **202** (**FIG. 18**) is shown engaged in end **174** of groove **192** (**FIG. 15**) on cassette body **156**. Movable member **172** is deployed allowing spike sheath **158** to be moved downwards and expose spike **163**.

It is contemplated that a cassette **150** may be provided as part of a kit of disposable elements for use with an infusate container infusion system such as that described in U.S. Patent Application No. 09/324,759, filed June 3, 1999. The cassette may also be provided alone as a disposable or reusable component of an infusate container infusion system. To enhance safety and to prevent accidental injury from spike **163**, it is contemplated that the cassette **150** of the present invention may be unpacked from a kit or other packaging or storing material with spike sheath **158** in an up or deployed position so that spike **163** is not exposed. Cassette **150** may be secured to

mating surface **200** by an automated mechanism (not shown) or manually. An infusate container (not shown) that is loaded upside down onto an infusate container holder (not shown) may then be positioned in place over the spike assembly **160** and against the spike sheath **158**. The infusate container holder is constructed so as to position the infusate container so that the infusate container stopper is aligned and centered with spike sheath **158**. The infusate container holder may also engage with lip **191** (**FIG. 16**) of spike sheath **158** and, when pushed down, drives the infusate container and spike sheath downwards exposing spike **163** and piercing the infusate container stopper. The infusate container holder may be positioned above spike sheath **158** and be manually moved down. As spike sheath **158** travels downwards, lever arm **166** is actuated such that stopcock **168** or other anti-free flow device allows flow of the liquid in the infusate container through infusate lumen **14b**. Cassette **158** and the peristaltic and intravenous tubing (IV) may then be purged, the IV tubing connected to an IV catheter, and an infusion process to a patient begun.

At the end of an infusion case, infusate infusion is stopped. The infusate container holder is pulled up and as it moves up it pulls the infusate container up and drags spike sheath **158** along with its lip **191**. The upwards travel of spike sheath **158** triggers lever arm **168** closing off infusate lumen **14b**. As the infusate container is unspiked, then, spike **163** is resheathed. Once the infusate container is removed, cassette **158** can be disengaged from mating surface **200**. Because infusate lumen **14b** is closed, none of the residual infusate left in cassette **158** and IV tubing can free flow to a patient still connected to the IV tubing. The IV tubing may then be disconnected from the IV catheter. The intravenous tubing and cassette **150** with the spike assembly **160** may then be discarded in a contaminated wastebasket.

If more than one infusate container is required for a given case, a first infusate container may be unspiked as described above while leaving cassette **150** secured to mating surface **200**. Closed infusate lumen **14b** prevents aspiration of air into the peristaltic and IV tubing such that there is no need to purge or prime the IV and/or peristaltic tubing again after changing infusate containers. A new infusate container may then be loaded in the infusate container holder and spiked as described above.

I claim:

1. A care system for alleviating patient pain, anxiety and discomfort associated with medical or surgical procedures said system comprising:

a patient health monitor device adapted so as to be coupled to a patient and generate a signal reflecting at least one physiological condition of the patient;

a drug conduit which carries a flow of the drugs from a drug container to the patient;

an infusion pump which effects the flow of drugs through the drug conduit;

a cassette removably interconnected to the infusion pump, wherein a portion of the drug conduit is placed adjacent to the cassette, such that the infusion pump operates in cooperation with the drug conduit to effect the flow of the drugs, and wherein the cassette is adapted to carry a drug container;

a drug delivery controller interconnected with the infusion pump that manages the delivery of one or more drugs from the drug container to the patient via the drug conduit;

a memory device storing a safety data set reflecting safe and undesirable parameters of at least one monitored patient physiological condition; and

an electronic controller interconnected between the patient health monitor, the drug delivery controller, and the memory device storing the safety data set; wherein said electronic controller receives said signal and in response manages the application of the drugs in accord with the safety data set.

2. A cassette for use with an intravenous infusion apparatus including a pumping mechanism which administers an infusate to a patient, wherein said cassette is removably attachable to the intravenous infusion apparatus, and wherein said cassette comprises:

a drug container entry mechanism having an infusate flow lumen, wherein infusate may flow from the container and into the flow lumen;

a pressure plate against which the pumping mechanism may act;

a means for attaching an infusate delivery conduit to the infusate flow lumen such that infusate can flow from the flow lumen into the delivery conduit;

a means for holding the infusate delivery conduit against the pressure plate such that the conduit is acted upon by the pumping mechanism in order to generate a flow of infusate from the container, through the flow lumen, into the delivery conduit, and to the patient; and

an indexing means for aligning the cassette when the cassette is attached to the intravenous infusion apparatus in a manner that allows proper administration of infusate to the patient.

3. A method for administering infusate to a patient, said method comprising the steps of:

attaching an infusate delivery conduit to an infusate flow lumen of a cassette, and aligning the conduit against a rigid pressure plate of the cassette;

attaching the cassette to an intravenous infusion apparatus such that the pressure plate aligns with a pumping mechanism provided with the infusion apparatus;

attaching an infusate container to an infusate container entry mechanism provided with the cassette;

attaching the infusate delivery conduit to a delivery means that is attached to the patient;

purging the infusion flow lumen and the infusion delivery conduit;

initiating the pumping mechanism in order to generate a flow of infusate from the container, through the flow lumen, into the delivery conduit, and to the delivery means attached to the patient; and

modulating the operation of the pumping mechanism based on measured or inferred effects of the infusate on the patient.

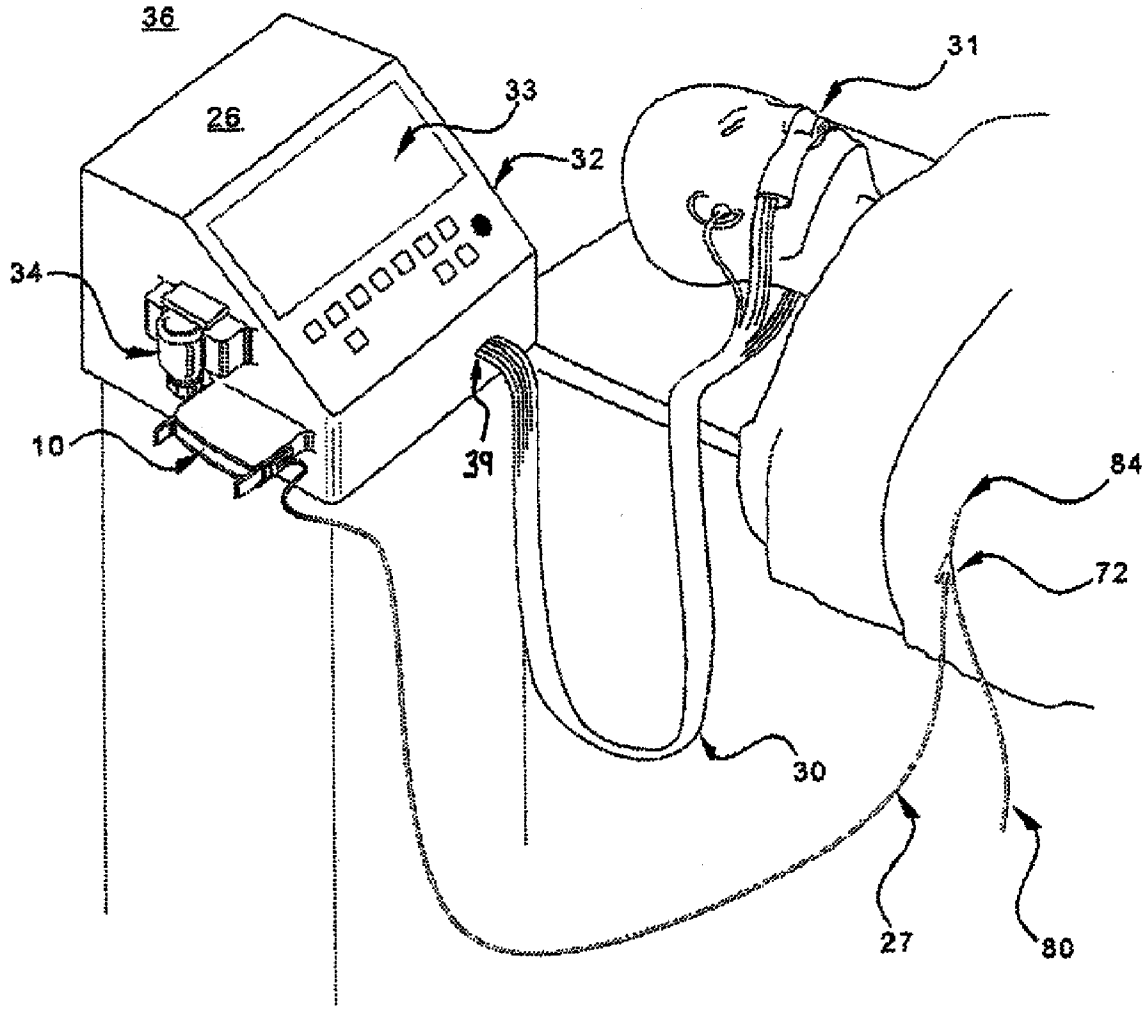

FIG. 1

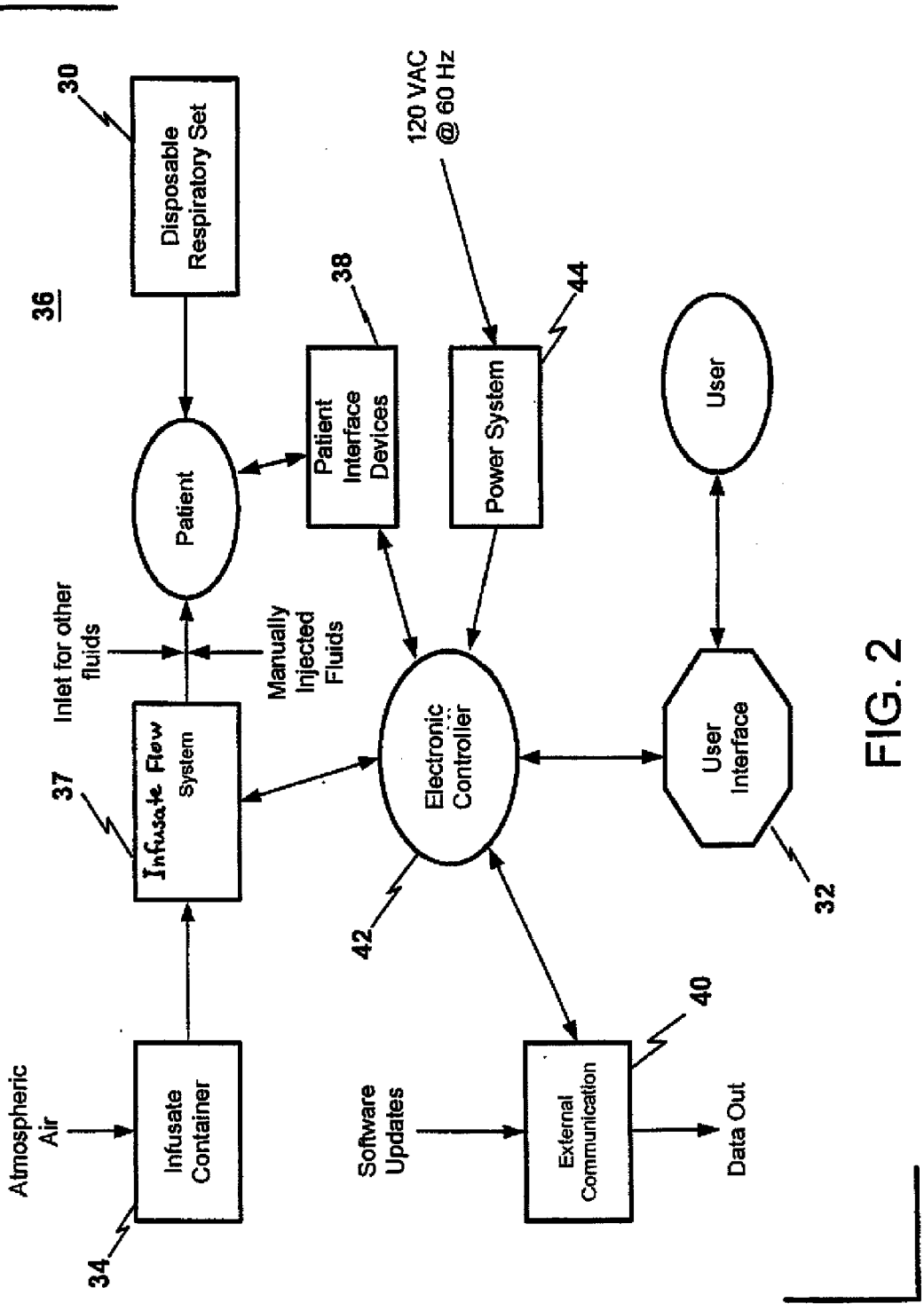
30
Disposable Respiratory Set
36
120 VAC @ 60 Hz
38
Patient Interface Devices
44
Power System
User
Patient
Inlet for other fluids
Manually Injected Fluids
37
Infusate Flow System
Electronic Controller
User Interface
42
32
Atmospheric Air
Infusate Container
34
Software Updates
External Communication
40
Data Out

FIG. 2

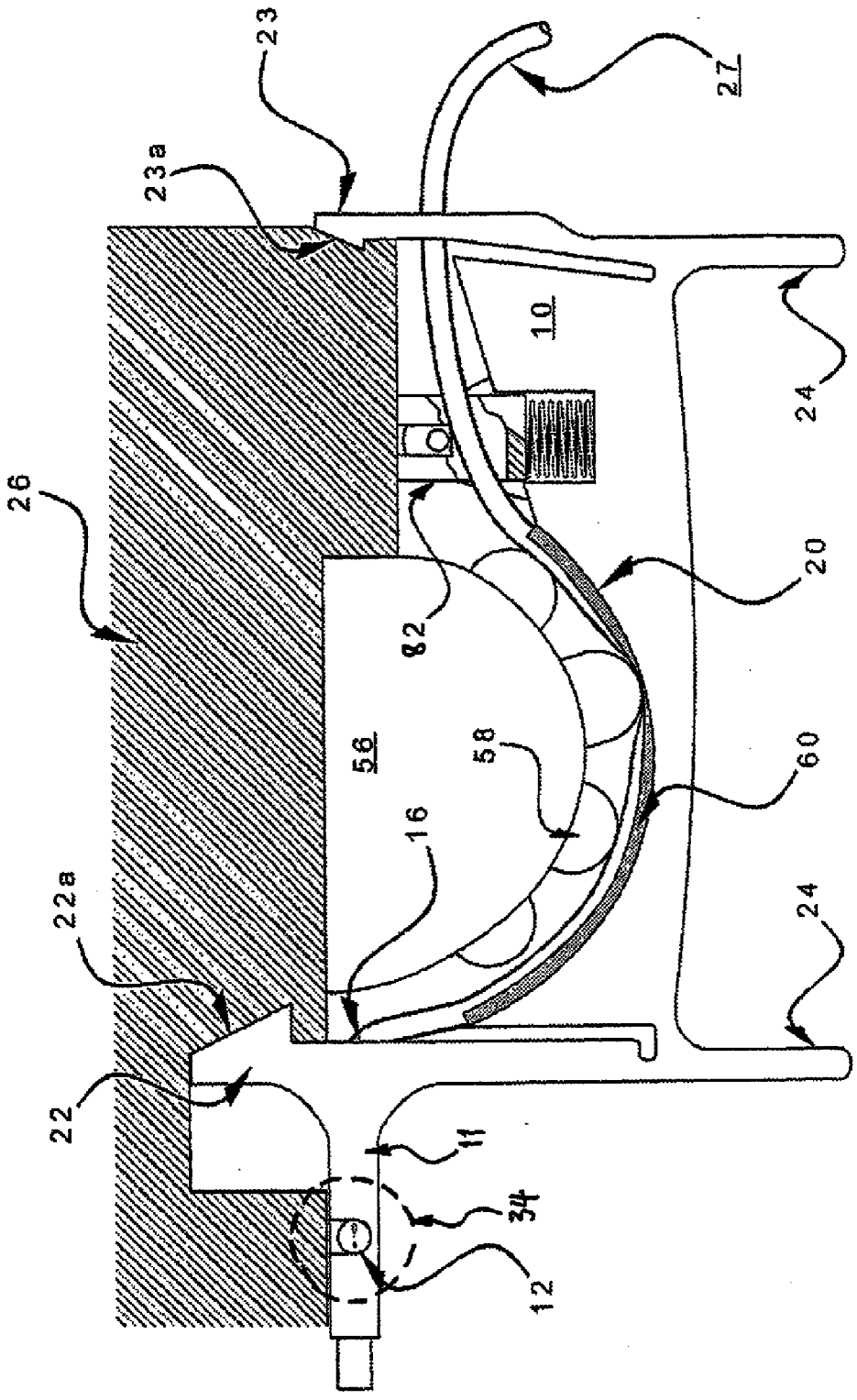

FIG. 3

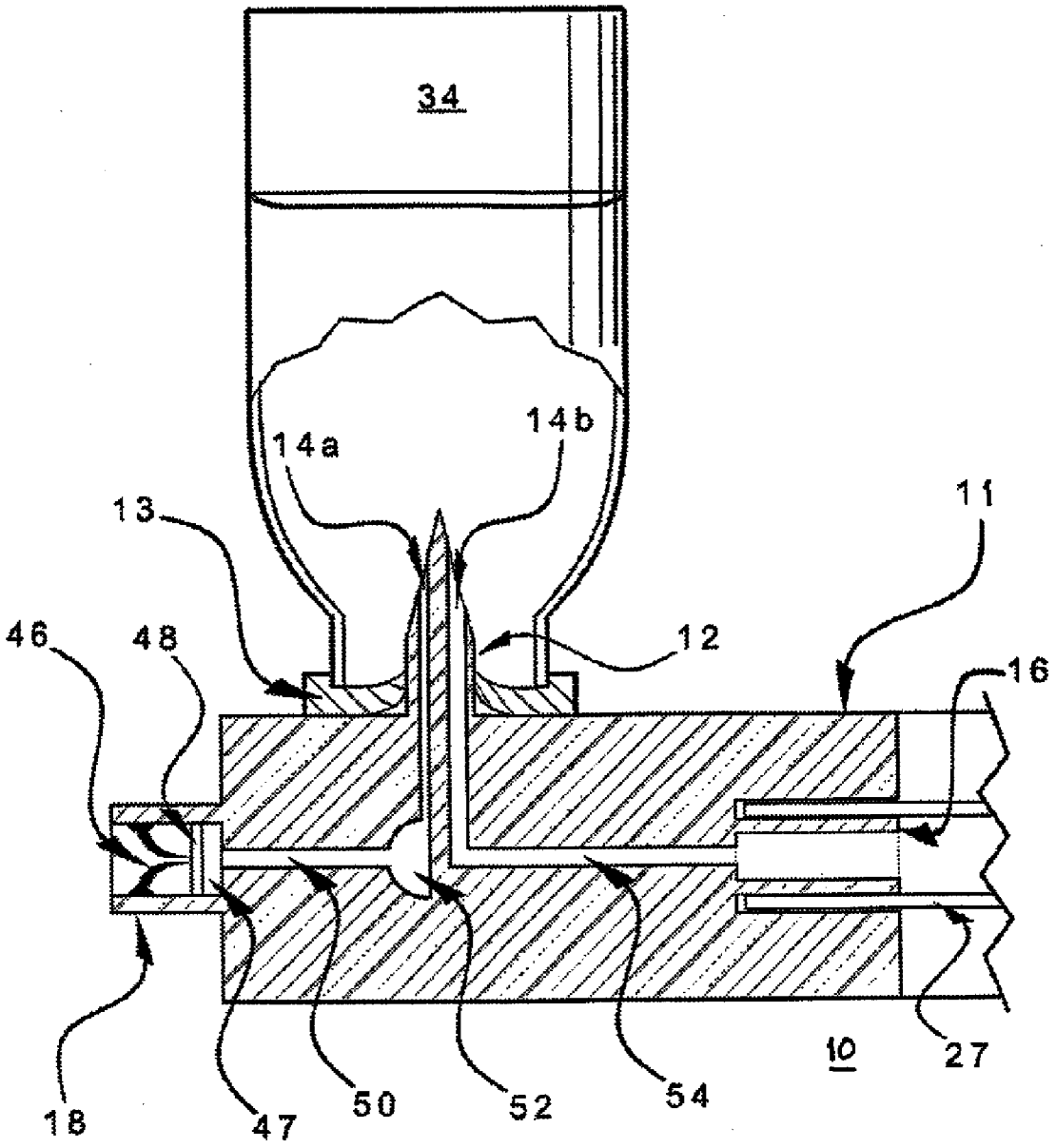

FIG. 4

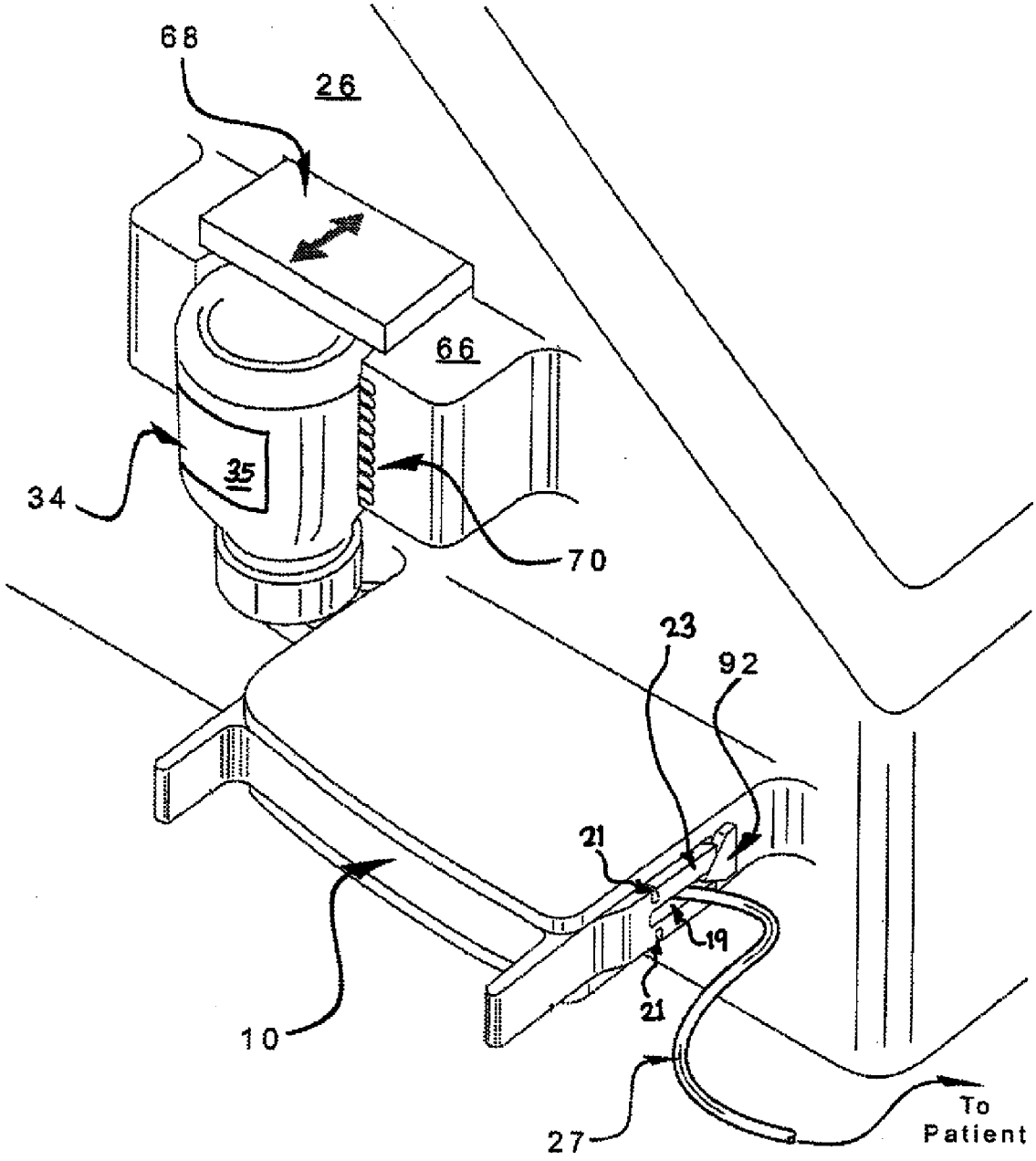

FIG. 5

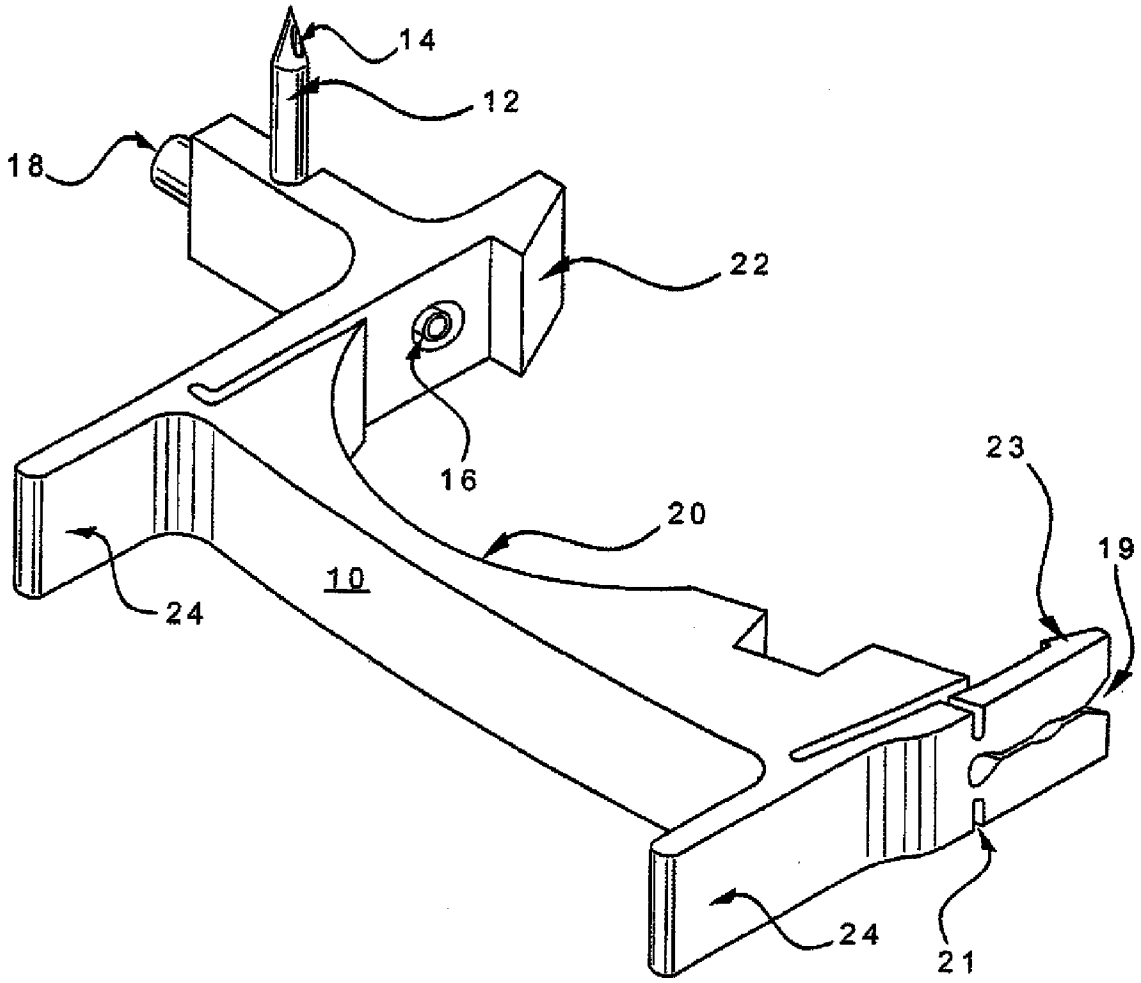

FIG. 6a

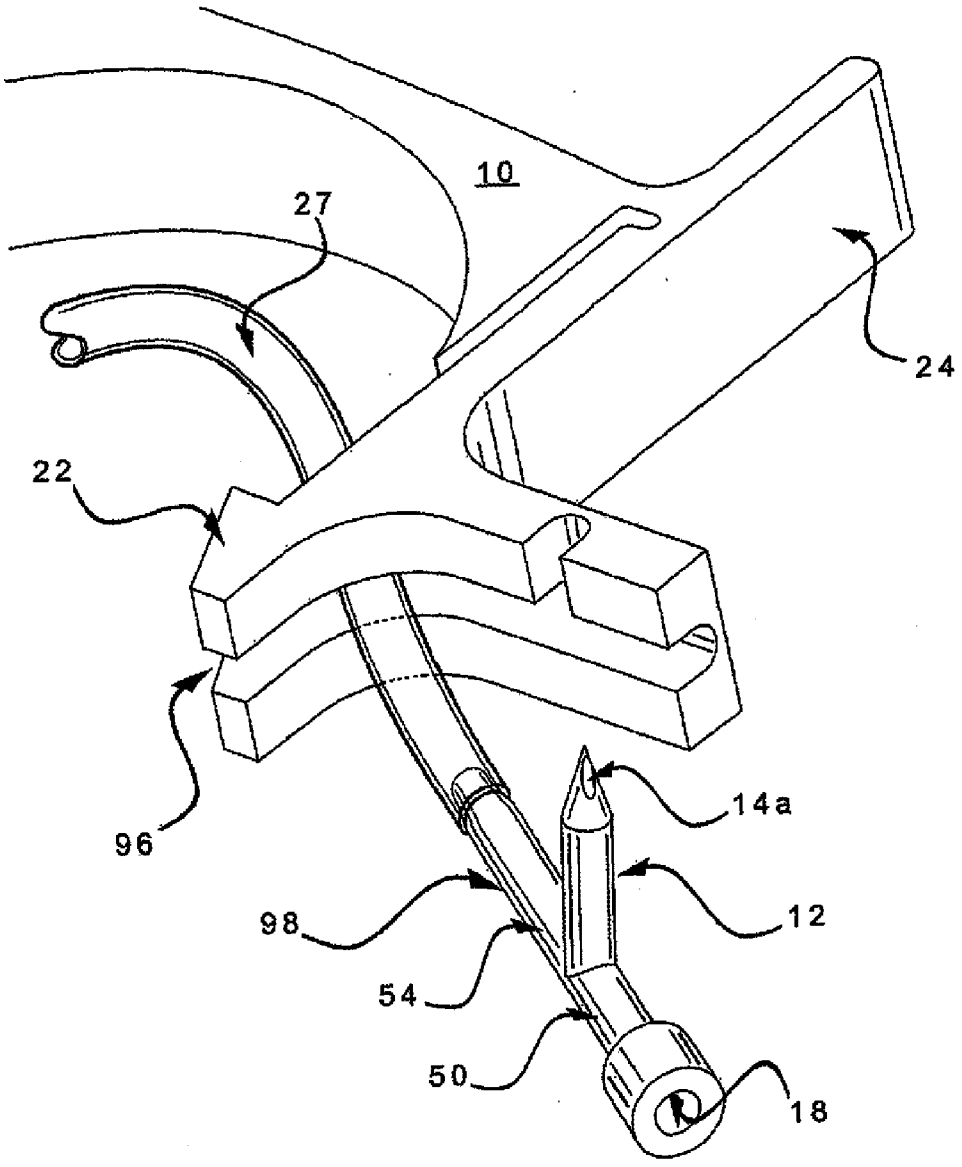

FIG. 6b

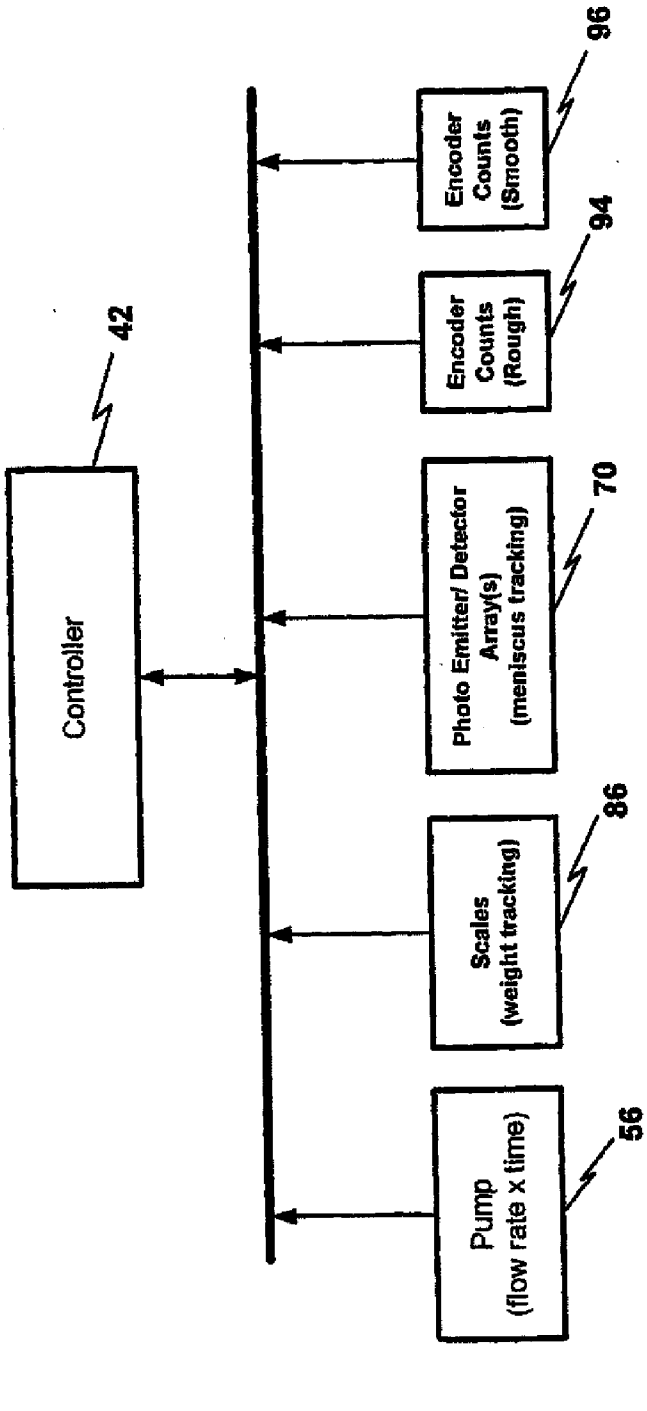
Controller
42
Encoder Counts (Smooth)
96
Encoder Counts (Rough)
94
Photo Emitter/ Detector Array(s) (meniscus tracking)
70
Scales (weight tracking)
86
Pump (flow rate x time)
56

FIG. 7

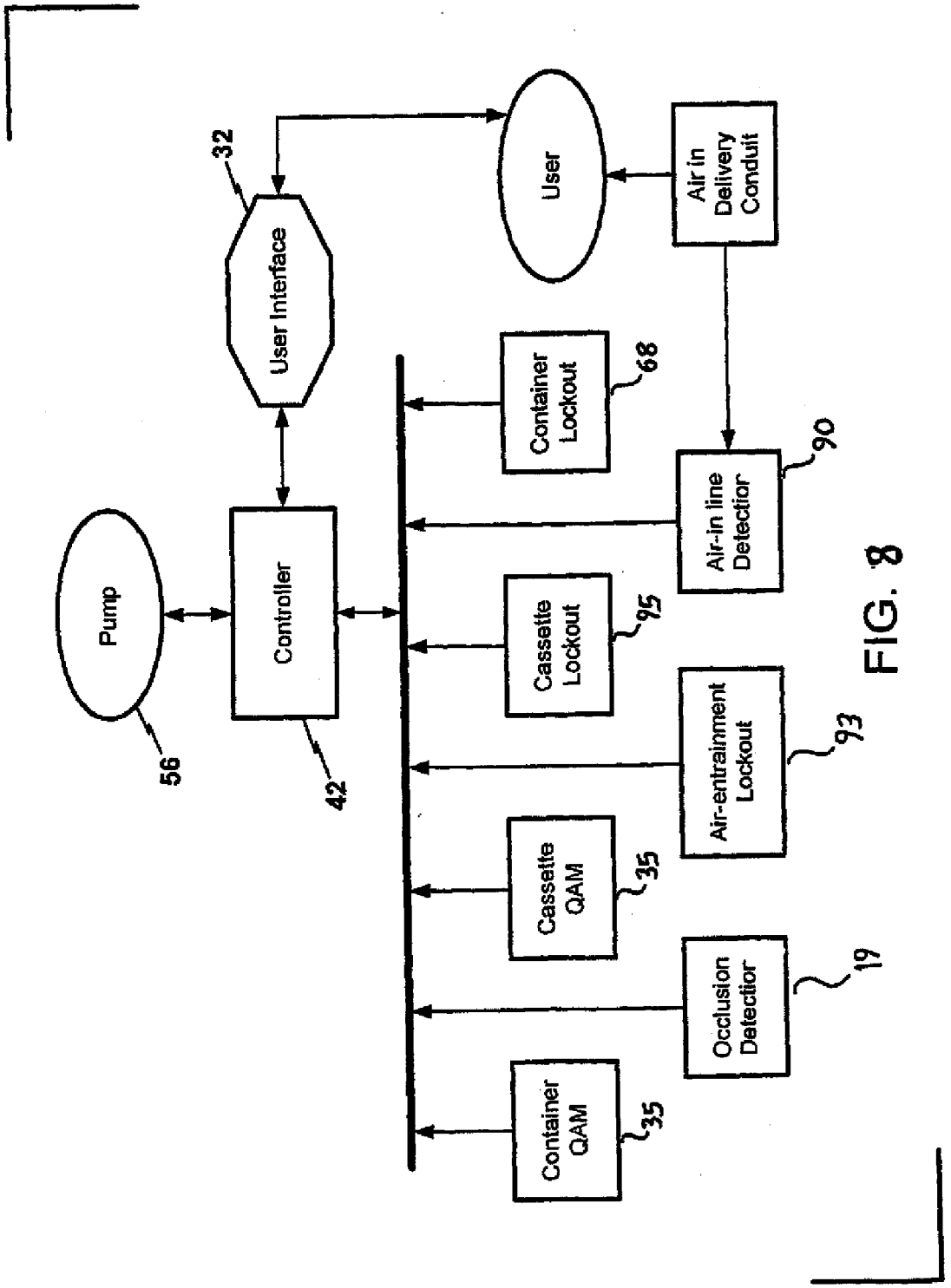
User
Air in Delivery Conduit
32
User Interface
Container Lockout
68
Air-in line Detector
90
Pump
Controller
Cassette Lockout
95
Air-entrainment Lockout
93
Cassette QAM
35
Occlusion Detector
19
Container QAM
35
56
42

FIG. 8

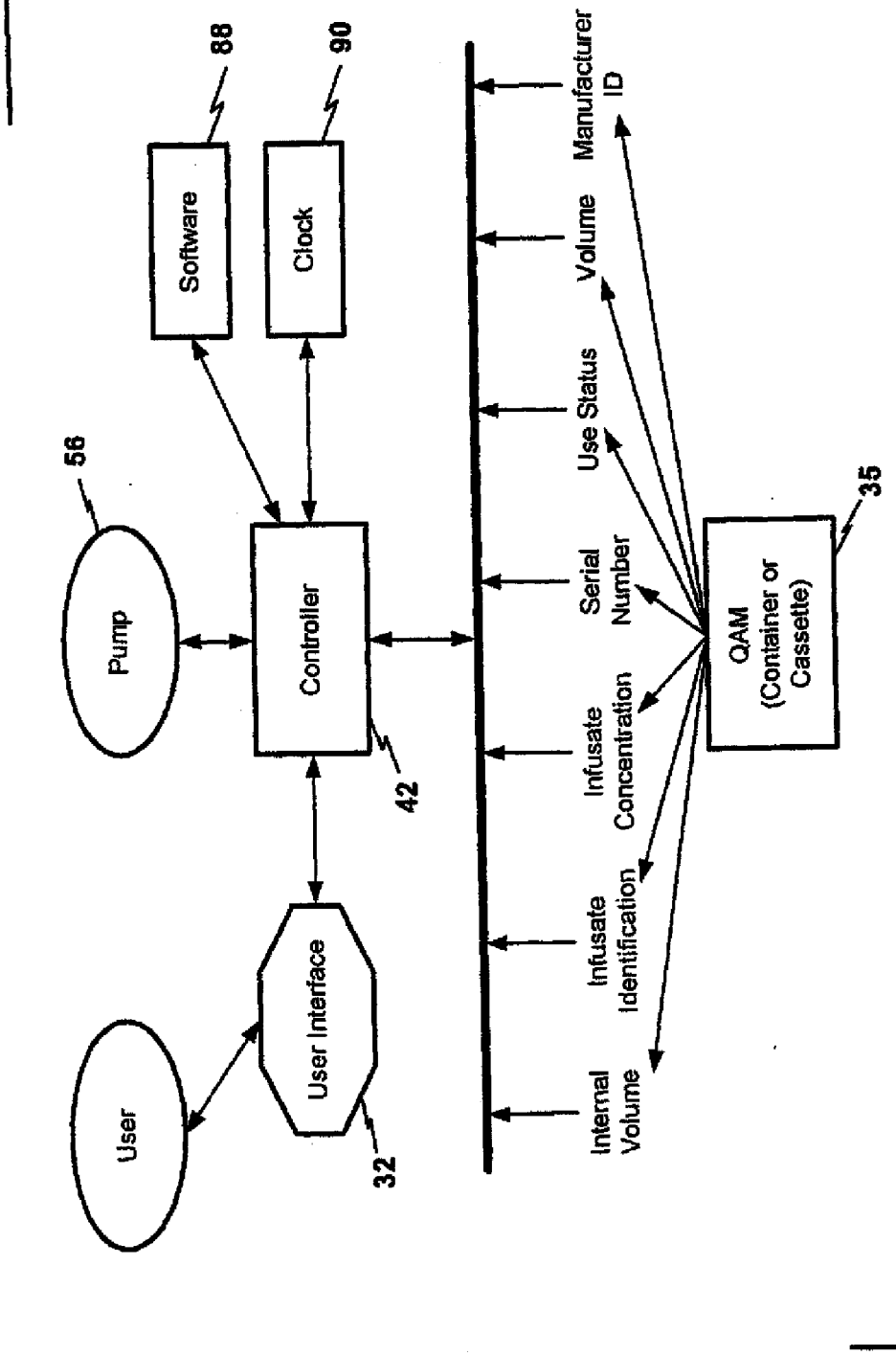
88
90
Software
Clock
56
Pump
Controller
42
User Interface
User
32
Manufacturer ID
Volume
Use Status
Serial Number
Infusate Concentration
Infusate Identification
Internal Volume
QAM (Container or Cassette)
35

FIG. 9

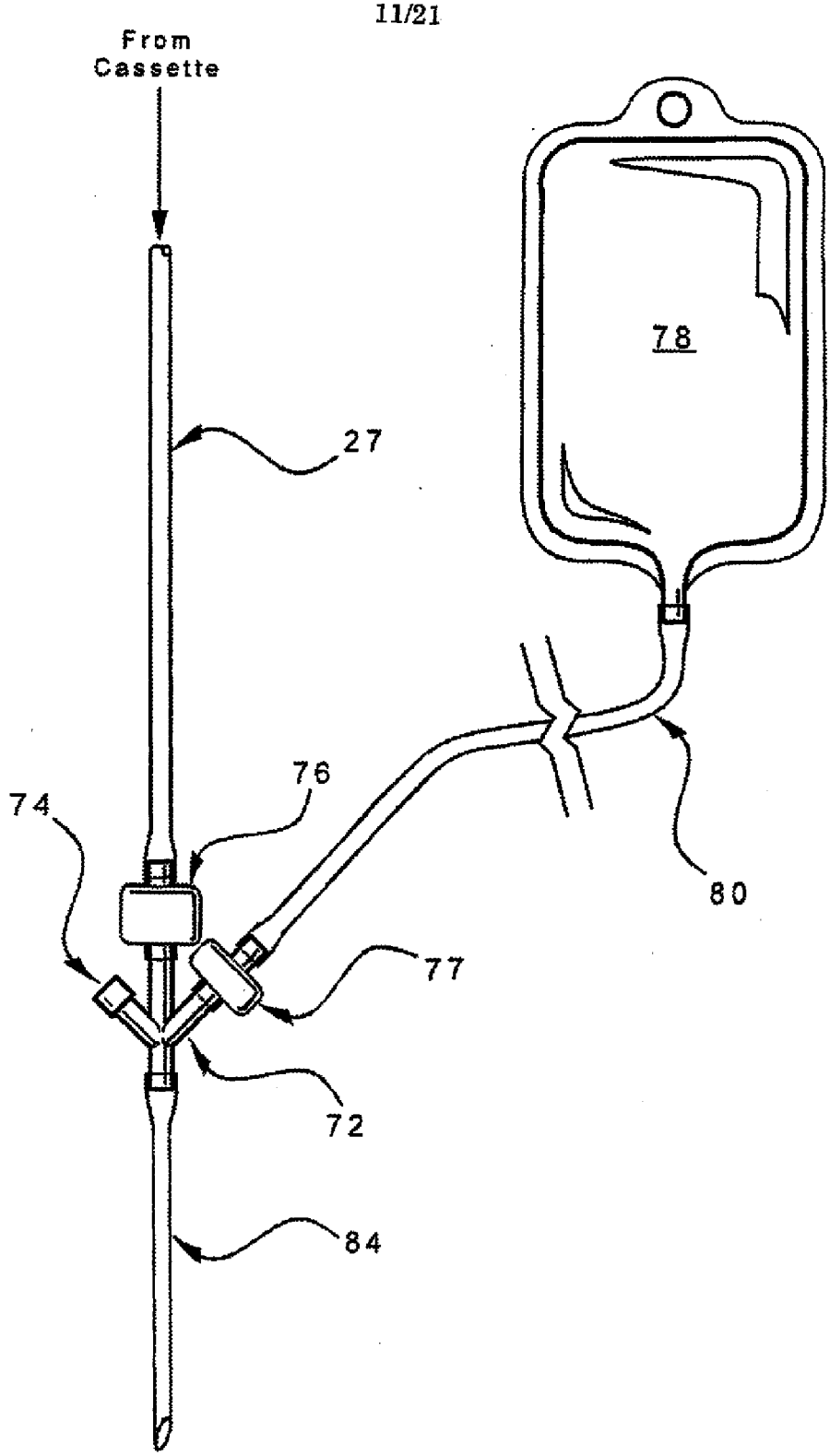

FIG. 10

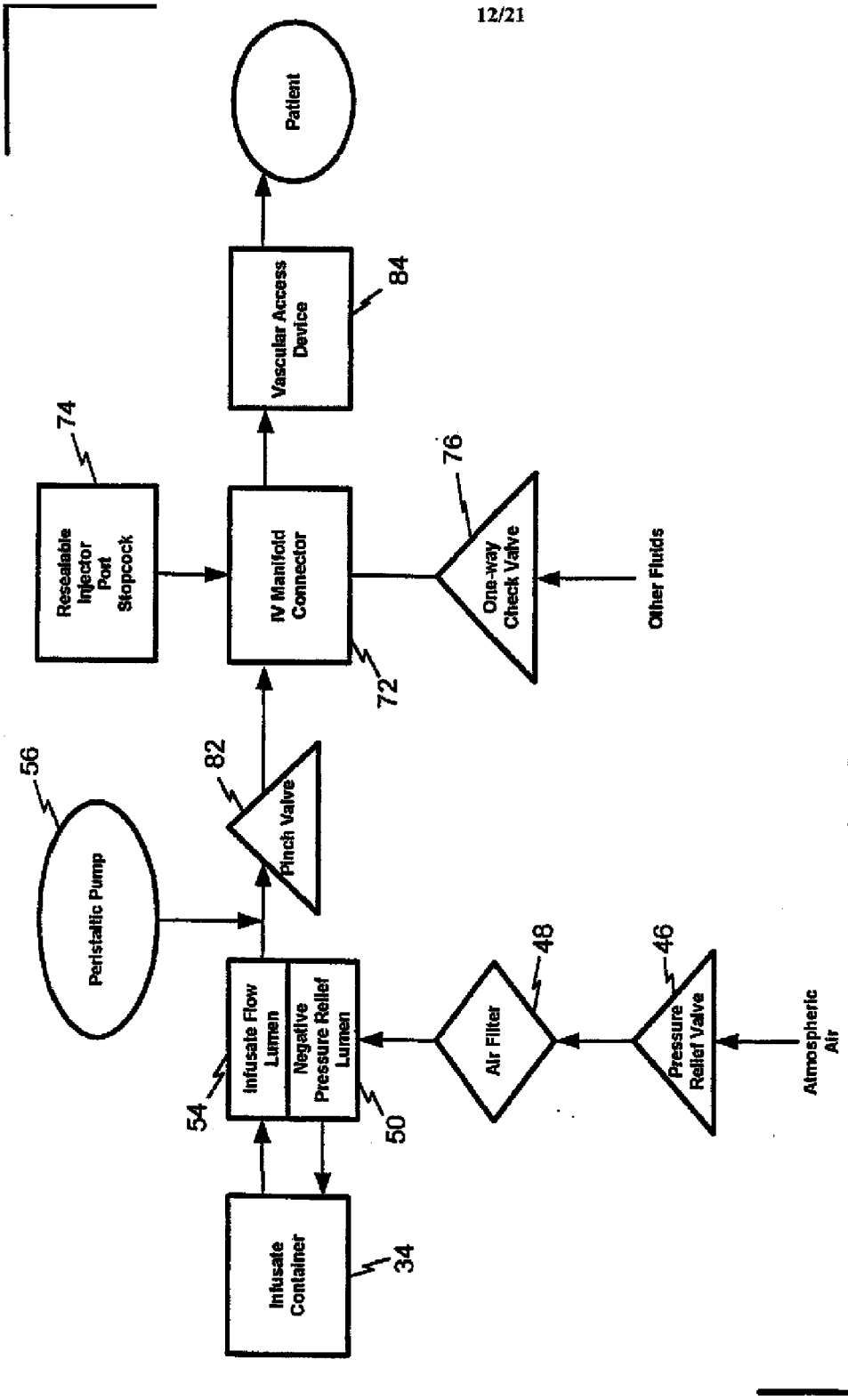
Patient
Vascular Access Device
84
Resealable Injector Port Stopcock
74
IV Manifold Connector
72
One-way Check Valve
76
Other Fluids
Pinch Valve
82
Peristaltic Pump
56
Infusate Flow Lumen
Negative Pressure Relief Lumen
54
50
Air Filter
48
Pressure Relief Valve
46
Atmospheric Air
Infusate Container
34

FIG. 11

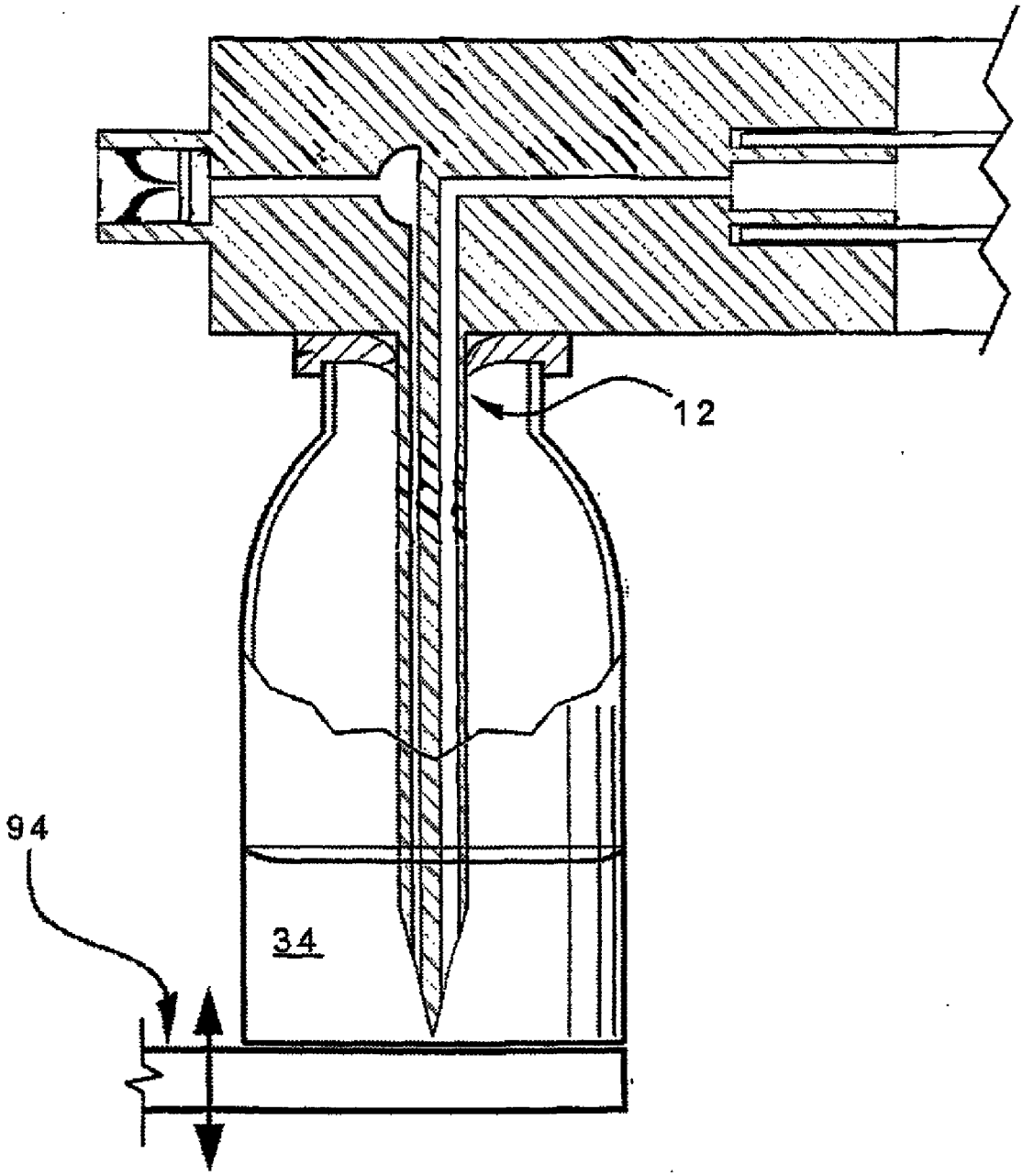

FIG. 12

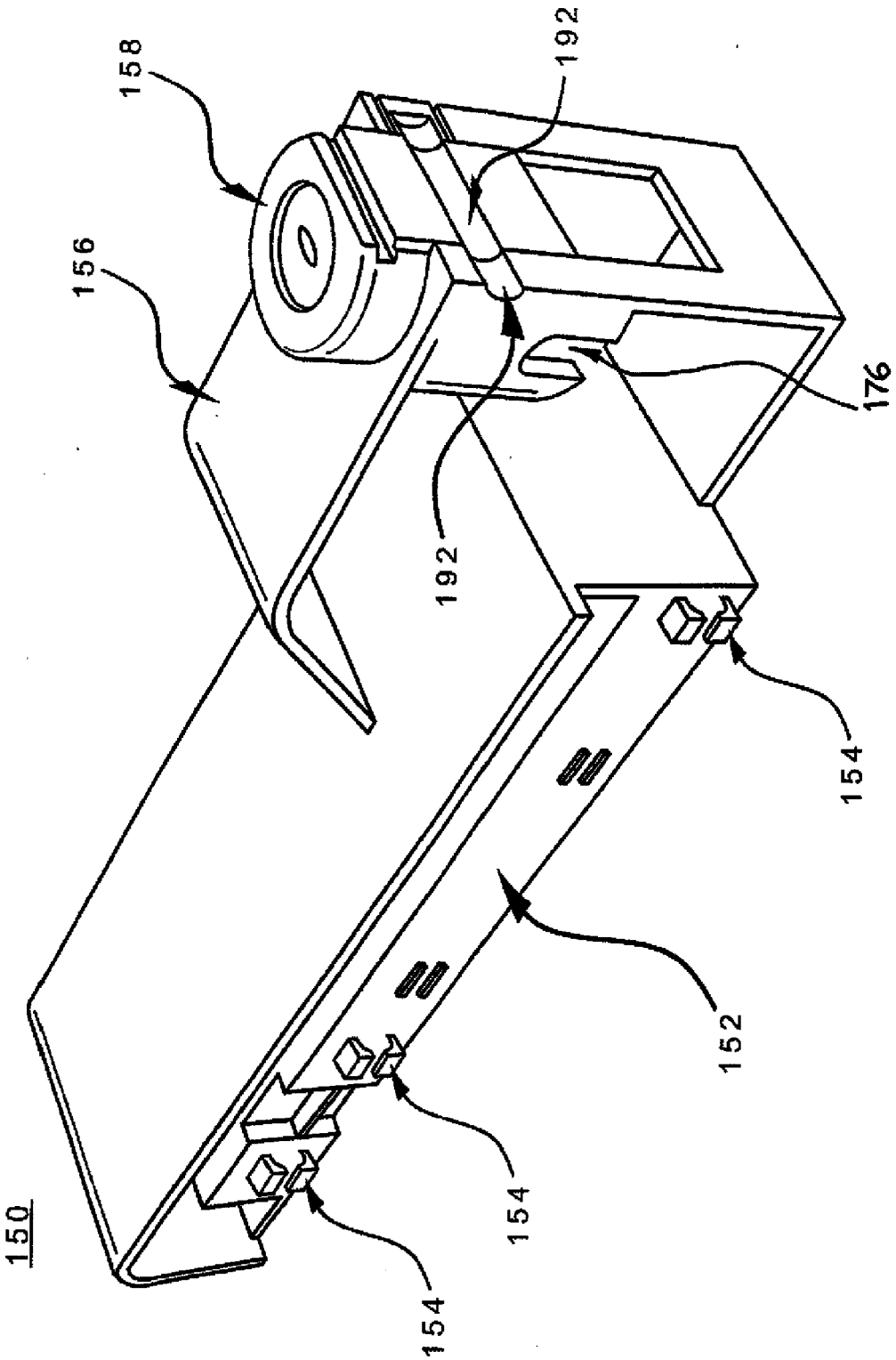

FIG. 13

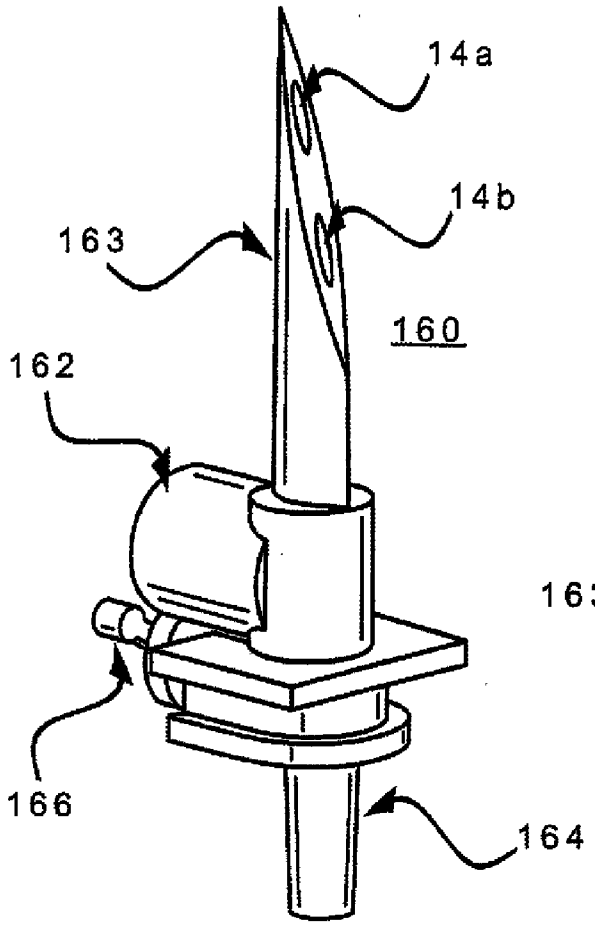

FIG. 14a

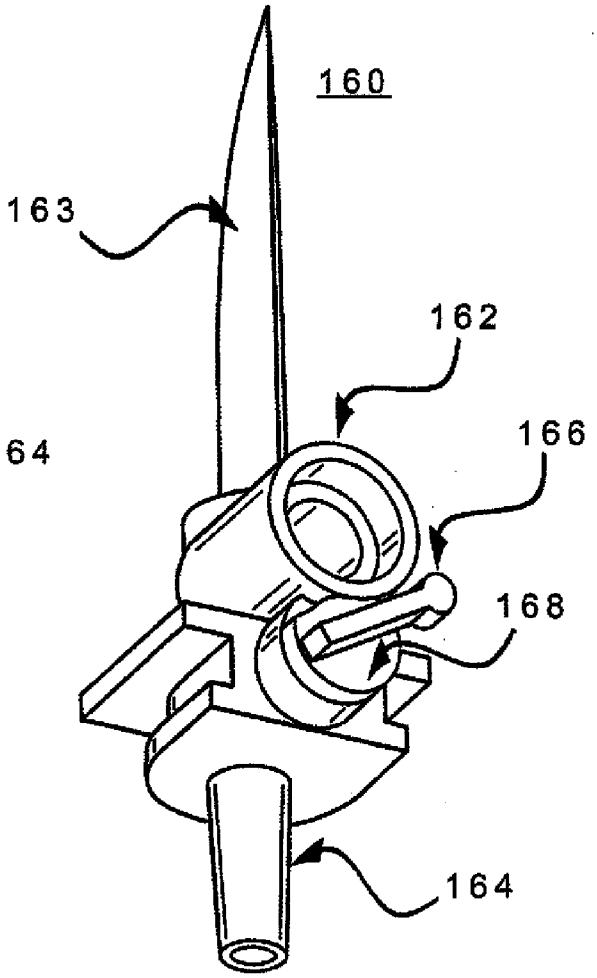

FIG. 14b

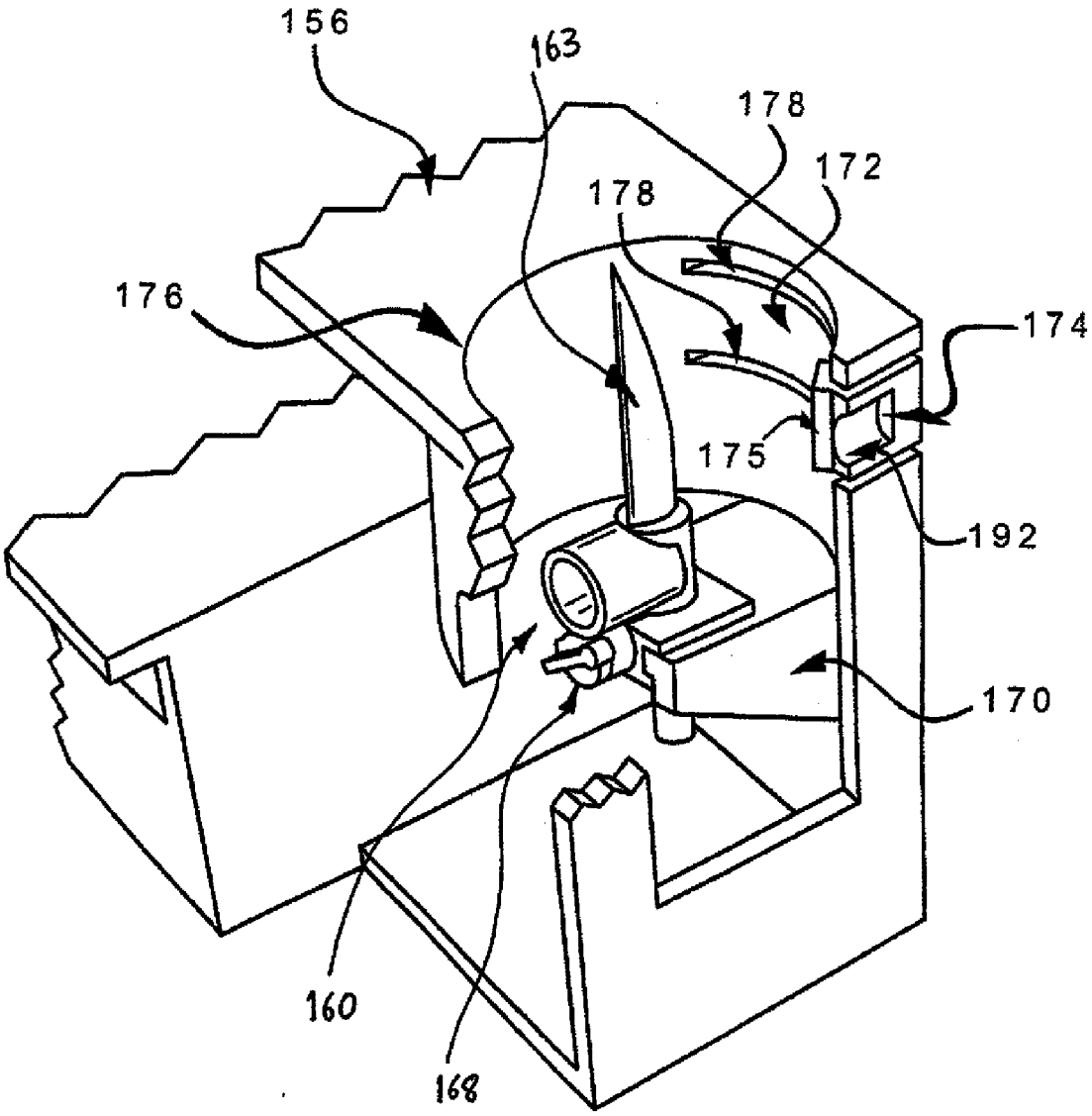

FIG. 15

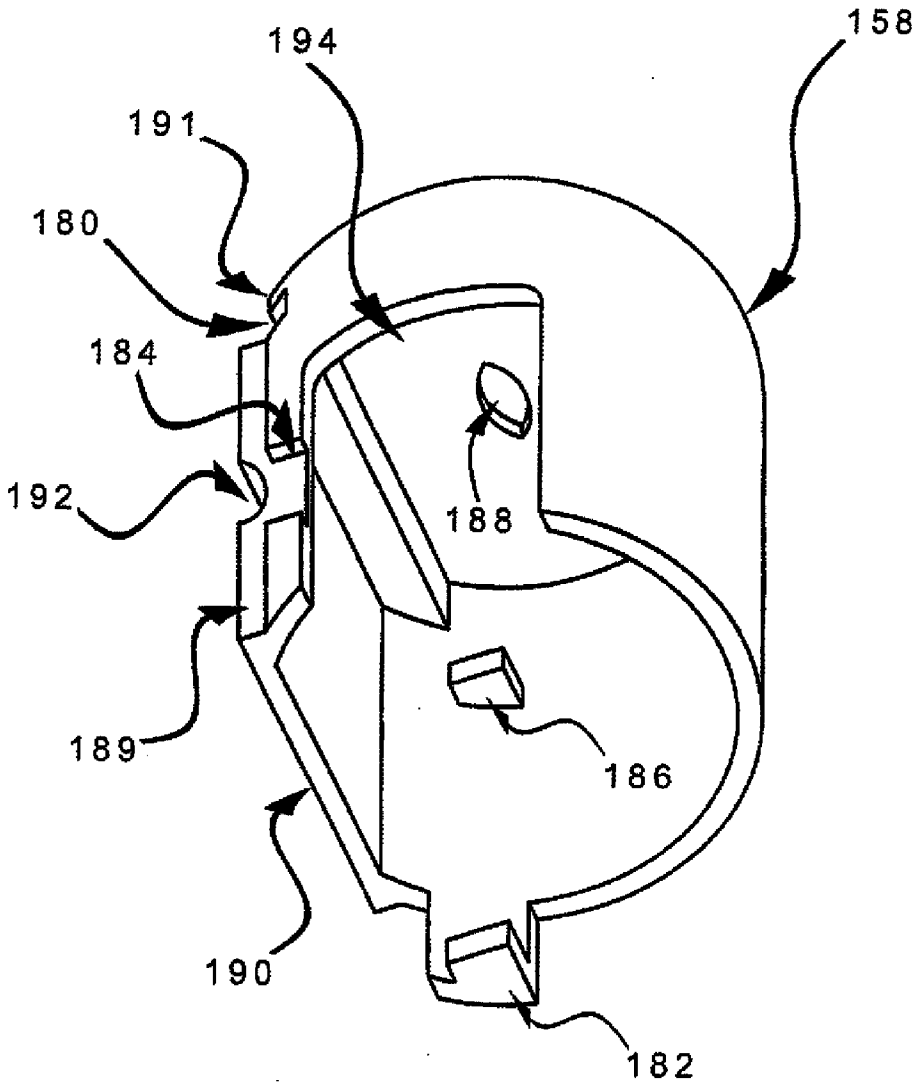

FIG. 16

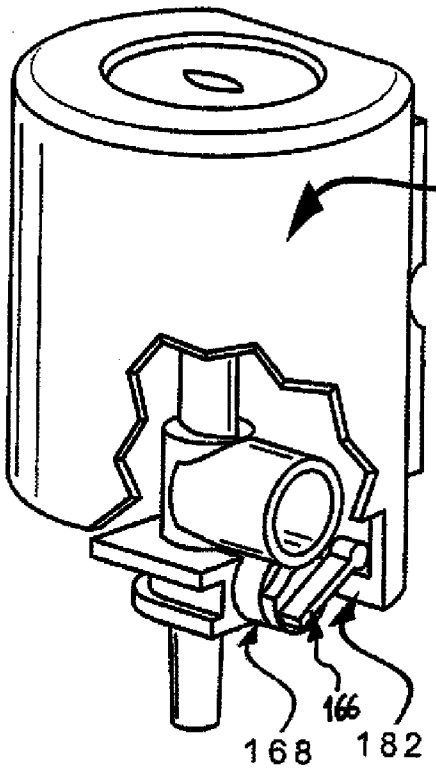

FIG. 17a

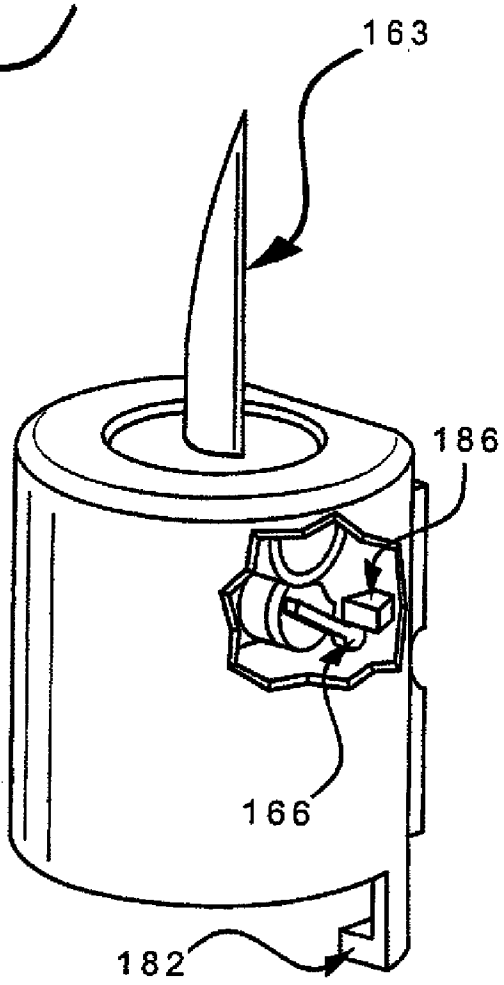

FIG. 17b

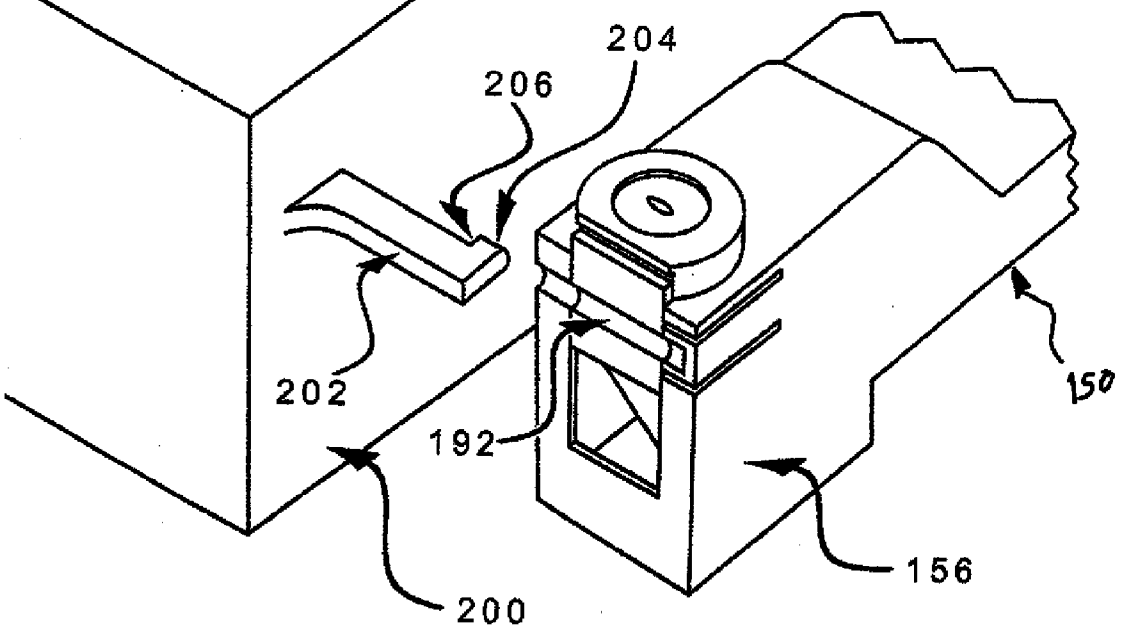

FIG. 18

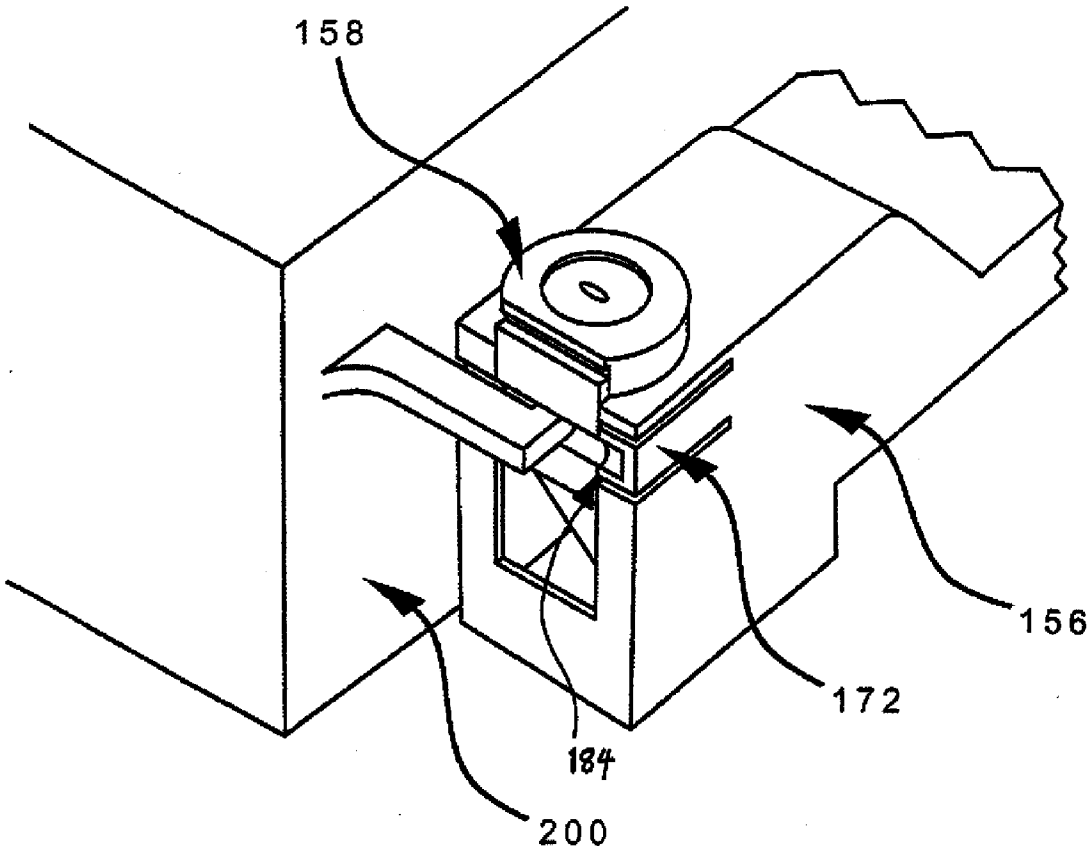

FIG. 19

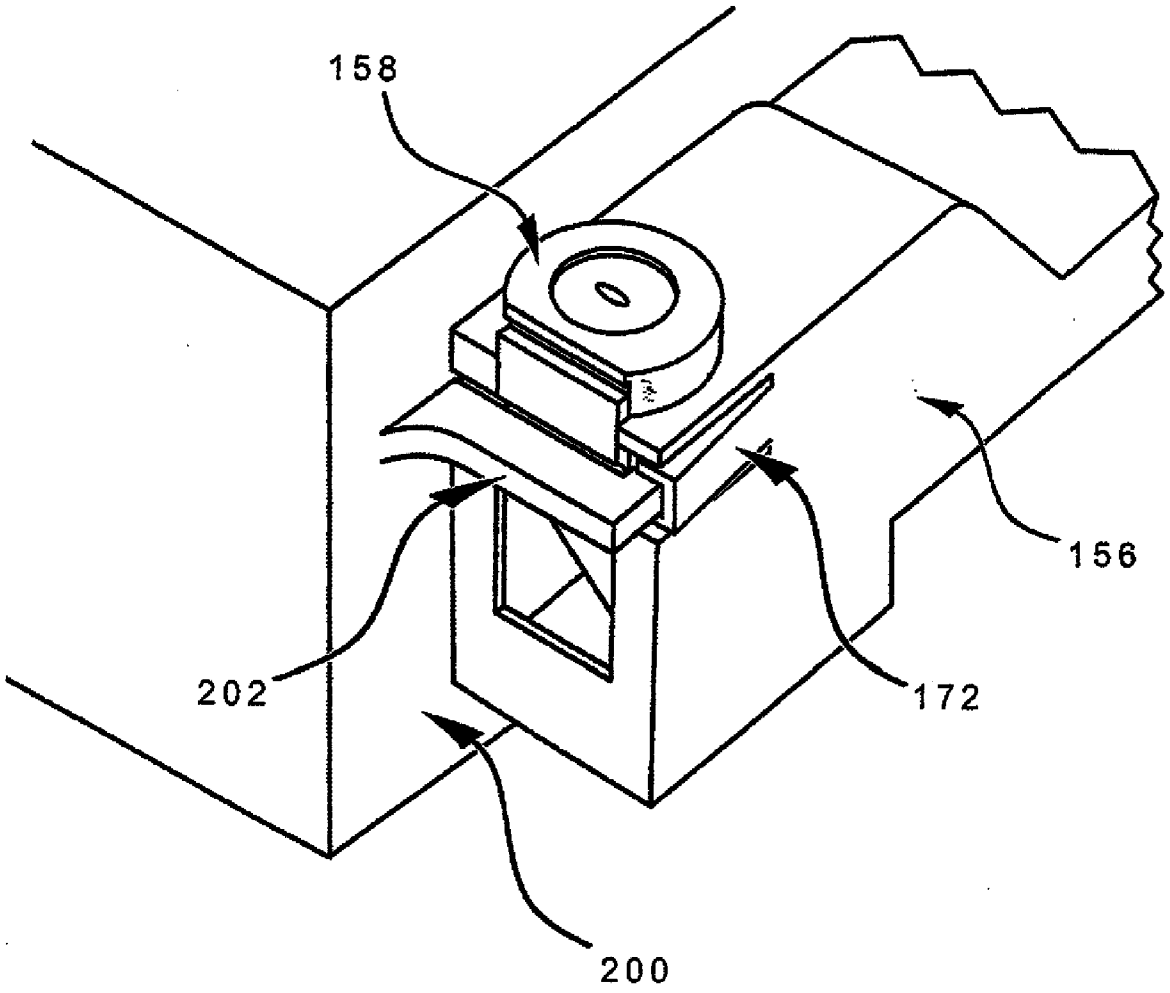

FIG. 20

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/24055

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/142

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 645 531 A (THOMPSON THOMAS C ET AL) 8 July 1997 (1997-07-08) column 8, line 6 - line 17 column 22, line 40 - line 45 figures	1
A		2
X	US 5 620 312 A (ZEILIG AVI ET AL) 15 April 1997 (1997-04-15) column 3, line 3 - line 20 column 6, line 51 - line 65 figures 1,3A,3B	2
Y		1
Y	WO 99 62403 A (SCOTT LAB INC) 9 December 1999 (1999-12-09) page 25, line 4 -page 26, line 20 figures 4A-5	1

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 November 2002	20/11/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Sedy, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/24055

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 531 698 A (OLSEN JAMES M) 2 July 1996 (1996-07-02) column 4, line 14 - line 36 column 5, line 10 - line 25 figures 1A,2	1,2
A	US 6 241 704 B1 (BLOMQUIST MICHAEL L ET AL) 5 June 2001 (2001-06-05) column 38, paragraph 2	1
A	US 6 063 052 A (HAVRILLA JOSEPH B ET AL) 16 May 2000 (2000-05-16) column 4, line 34 - line 46 abstract; figures 1,2	1,2
A	US 5 431 627 A (PASTRONE GIOVANNI ET AL) 11 July 1995 (1995-07-11)	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/24055

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 3
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/24055

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/24055

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